



March 11, 2022

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: CMS-1774-PN; Medicare Program: Announcement of Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition; Notice with request for comment, Federal Register (Vol. 87, No. 27), February 9, 2022

Dear Administrator Brooks-LaSure:

The American Hospital Association (AHA) represents 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and 43,000 health care leaders who belong to our professional membership groups. The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. Together, our members provide patients and communities with access to high-quality, affordable care across settings in both urban and rural areas. They include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services, including in communities that would be impacted by the expansion application of Doctors Hospital at Renaissance (DHR). The AHA and FAH appreciate the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the above Notice with Request for Comment (Notice) published in the Federal Register (87 Fed. Reg. 7471) on February 9, 2022.

***The AHA and FAH urge CMS to deny DHR's request for an exception to the prohibition on expansion of the facility capacity of a physician-owned hospital.*** CMS is not obligated by statute or regulation to grant an expansion request to any facility that satisfies the "high Medicaid facility" exception criteria, and CMS should deny DHR's request because the

requested expansion is inconsistent with Congress’s intent, does not serve a valid public policy purpose, and would set a bad precedent.

Further, the current exception request clearly illustrates how the “high Medicaid facility” exception, as amended in the 2021 hospital outpatient prospective payment system (OPPS) final rule published on December 2, 2020, opens the door for requests that may technically meet, but clearly violate the spirit of the general statutory ban on physician-owned hospitals. ***Accordingly, we also urge CMS to reverse the 2020 amendments to the “high Medicaid facility” exception.***

## ***1. CMS Has Discretion to Deny the Requested Expansion***

In Section 1877(i)(3) of the Social Security Act, Congress conferred the Secretary with the *discretion to consider* certain physician-owned hospital requests for facility expansion, despite the statutory prohibition on physician-owned hospitals expanding beyond their licensed capacity as of March 23, 2010. Both the statute and the regulations state that a hospital that meets the criteria for a “high Medicaid facility” may “*apply for*” or “*request*” an exception to the expansion limits.<sup>1</sup> Nowhere does the statute or the regulations state that a facility that meets the “high Medicaid facility” criteria is *entitled* to an exception to the prohibition on facility expansion or that CMS is *obligated* to grant any particular exception. Rather, the statutory and regulatory default is that a physician-owned hospital that expands after March 23, 2010, is no longer entitled to an exception to the prohibition on physician self-referrals and cannot submit Medicare or Medicaid claims for designated health services where a physician owner or investor referred the beneficiary for the services. The only circumstance in which an expansion is permitted is where the Secretary exercises his discretion and grants an expansion exception request to a qualifying facility.

Although the Secretary is required to deny a request that does not comply with the statutory and regulatory requirements, the Secretary may also deny a request based on additional, case-specific considerations, including those raised by commenters. This discretion to consider additional information beyond the three high Medicaid facility criteria is apparent from the community input requirements that are a part of the exception request process. The statute requires that the exception request process include an opportunity for community members “to provide input with respect to” the request.<sup>2</sup> Likewise, under 42 C.F.R. § 411.632(c)(5), community members “may provide input with respect to the hospital’s request” for a high Medicaid facility expansion through “written comments.”<sup>3</sup> Neither the statute nor the regulation limits public comment to data or information concerning the high Medicaid facility criteria. In fact, when adopting this regulation, the Secretary acknowledged his discretion to consider the full range of potential community input, stating that he was “not restricting the type of community input that may be submitted.”<sup>4</sup> This opportunity for community input on all aspects

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<sup>1</sup> Social Security Act § 1877(i)(3)(A)(i); 42 C.F.R. § 411.362(c)(1).

<sup>2</sup> Social Security Act § 1877(i)(3)(A)(ii).

<sup>3</sup> This regulation implements the statutory requirement that the Secretary provide community members with an opportunity to provide input with respect to an expansion exception request. Social Security Act § 1877(i)(3)(A)(ii).

<sup>4</sup> 76 Fed. Reg. 74122, 74523 (Nov. 30, 2011).

of the request suggests that the Secretary is not limited to considering the three high Medicaid facility criteria when considering whether he should exercise his discretion to grant or deny an exception request. ***Indeed, the AHA and FAH believe that DHR's request to expand into a wholly new and distant community should be properly denied for the reasons explained further below.***

Moreover, the purpose of the high Medicaid facility exception – preserving the Secretary's discretion to promote access to care for Medicaid recipients by permitting certain expansion exception requests – reinforces our contention that Congress purposefully omitted automatic entitlement for any hospital that meets the criteria for “high Medicaid facility” status. As explained further below, the general acute care hospitals in Cameron County, Texas are adequately providing for the needs of Medicaid beneficiaries in the County; the creation of a distant second campus of DHR in Cameron County is not warranted by beneficiary needs and clearly violates the spirit and intent of the statutory prohibition on physician-owned hospitals under the Stark law.

## ***2. The Request to Expand to a New Community Should Be Denied Based on Community Need and Beneficiary Interests***

In its application, DHR is seeking to serve an entirely different community than it does in its main facility. It would accomplish this by building a new inpatient facility approximately 55 miles away from its main hospital campus in a different county. Previously, this extraordinary request for a distant, off-campus provider-owned hospital expansion would have been denied under 42 C.F.R. § 411.362(c)(6)(ii), which prior to 2021 limited expansion requests for high Medicaid facilities to expansions on the hospital's main campus. Although a high Medicaid facility may submit an expansion exception request for an off-campus location under the amended regulation, DHR's request should be denied in light of public policy concerns, community needs, and beneficiary interests.

***CMS Should Closely Scrutinize Public Policy Considerations When Evaluating an Off-Campus Expansion Request for a Physician-Owned Hospital.*** First, DHR's expansion request is troubling considering the extraordinary distance between DHR's proposed Brownsville campus and its main hospital campus in Edinburg. The new facility would not be a typical provider-based location that operates off the main hospital campus but still serves the same or a closely related, nearby community; instead, it would be among the most extreme of off-campus facilities, serving a distinct community over 50 miles away in another county. The AHA and FAH continue to believe that the recent amendments to the high Medicaid facility expansion request requirements are inappropriate for the reasons set forth in their respective letters opposing the 2020 amendments to 42 C.F.R. § 411.362 (*see* AHA Ltr., pp. 35 – 37 (Oct. 5, 2020), attached hereto as Appendix A; FAH Ltr., pp. 23 – 29 (Oct. 5, 2020), attached hereto as Appendix B) and urge CMS to reverse these problematic amendments that open the doors for expansion requests that fail to serve the needs of Medicaid beneficiaries. CMS properly exercised its authority under section 1871 and 1877(i)(3)(A)(i) of the Social Security Act in the 2012 OPBS Final Rule to apply the on-campus limitation to both applicable hospitals and high

Medicaid facilities.<sup>5</sup> Congress, in permitting the Secretary to consider expansion exception requests from high Medicaid facilities, imposed county-specific criteria,<sup>6</sup> reflecting an expectation that the Secretary would limit high Medicaid facility expansions to the same county in which the expanding physician-owned hospital is located. This expectation—apparent in the plain text of the statute—is best served by applying the location limitation for applicable hospital expansions to high Medicaid facility expansions.

Even under the amended regulations, however, CMS is not obligated to grant DHR’s request, and the AHA and FAH urge CMS to consider all relevant facts and circumstances -- including the extraordinary distance between DHR’s main campus in Edinburg and the proposed expansion site in Brownsville. Based on this and other case-specific factors, such as DHR’s Medicaid and uncompensated care numbers and data showing adequate hospital services in Brownsville, the AHA and FAH urge CMS to decline DHR’s request for an exception to the prohibition on physician-owned hospital expansions.

In amending the regulation to eliminate the on-campus expansion requirement for high Medicaid facilities, CMS relied on the operation of “distance limitations related to the location of off campus facilities and provider-based departments” to address concerns that high Medicaid facilities would expand into “additional campuses far away from the patients the expansion is intended by statute to serve.”<sup>7</sup> CMS cited “section 1833(t)(B)(i) of the Act and § 413.65(e)(3)(v)(F)” in support of the assertion that the distance limitations for off-campus provider-based departments would suffice to protect against expansions to distant communities. However, neither of these provisions operates to impose a distance limitation applicable to DHR. Section 1833(t)(21)(B)(i) of the Social Security Act<sup>8</sup> defines an “off-campus outpatient department of a provider” but does not itself impose any distance limitation for off-campus facilities. And § 413.65(e)(3)(v)(F) does not impose a distance limitation—rather, it requires that a provider-based department of a children’s hospital be located *more than* 35 miles from the nearest other neonatal intensive care unit. As a general matter, a provider-based facility must typically be “located within a 35-mile radius of the campus” of the main provider.<sup>9</sup> But the provider-based regulations also permit the establishment of some provider-based facilities in far-flung communities.<sup>10</sup> DHR’s request exploits the flexibility of the provider-based regulations to its fullest extent, relying on DHR’s contract with Cameron County and its disproportionate share adjustment percentage in an effort to satisfy the alternative standard under 413.65(e)(3)(ii).<sup>11</sup>

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<sup>5</sup> 76 Fed. Reg. 74,121, 74,524 (Nov. 30, 2011).

<sup>6</sup> Social Security Act § 1877(i)(3)(F)(i), (ii).

<sup>7</sup> 85 Fed. Reg. 85,866, 86,257 (Dec. 29, 2020).

<sup>8</sup> Due to an apparent typographic error, the preamble did not include the paragraph number in this citation, but as paragraph (21) is the only paragraph of section 1833(t) with a subparagraph (B)(i) referencing an off-campus facility or a provider-based department, the FAH understands that the intent was to cite to section 1833(t)(21)(B)(i).

<sup>9</sup> 42 C.F.R. § 413.65(e)(3)(i).

<sup>10</sup> *E.g.*, 42 C.F.R. § 413.65(e)(3)(ii).

<sup>11</sup> It is also worth noting that Texas law requires that all inpatient building be within a 30-mile radius of the main address of the hospital. Tex. Health & Saf. Code § 241.023(c-1)(2); Tex. Admin. Code, tit. 25, § 133.2(47)(B)(ii). The provider-based rules require that a remote hospital

It is evident that the amendment eliminating the on-campus requirement for high Medicaid facility expansions was made with the assumption that the typical 35-mile “distance limitation” for provider-based departments would be adequate to prevent high Medicaid facilities from expanding to distant locations. Because DHR’s current expansion request exceeds these assumed distance limitations, it should be denied. At a minimum, the AHA and FAH urge CMS to closely scrutinize the request in light of larger policy objectives and to decline to permit the requested expansion as unnecessary to serve the needs of Medicaid beneficiaries in Cameron or Hidalgo County.

***DHR is Not the Highest Medicaid Provider in Hidalgo County.*** DHR relies on discharge data to argue that it has the highest percentage of Medicaid admissions in Hidalgo County (where DHR’s main campus is located). But data on actual Medicaid days indicate that DHR’s inpatient Medicaid utilization is lower than other hospitals in Hidalgo County. Indeed, according to the Texas Medicaid DSH qualification file, DHR’s Medicaid days as a percentage of total days was 48.65% in 2020 and 46.874% in 2021.<sup>12</sup> These percentages are lower than those for Mission Regional Medical Center (56.67% in 2021) and Knapp Medical Center (50.65% in 2020 and 55.12% in 2021).<sup>13</sup> Although the high Medicaid facility criteria focus on Medicaid admissions rather than Medicaid days, CMS has discretion to consider this data in determining the overall benefit (or lack thereof) of the proposed expansion.

***Patient Access Considerations Do Not Warrant DHR’s Expansion into Cameron County.*** DHR has not identified any reason that an exception to the prohibition on new or expanded physician-owned hospitals is needed in order to address patient access issues in Cameron County. In fact, in its application for a waiver to the 30-mile distance limitation in Texas’ hospital licensing law, DHR presented data showing that Cameron County has *more* inpatient acute care beds per capita than Hidalgo County (2.6 beds vs. 2.1 beds per 1,000 people) and that the per capita inpatient bed capacity in Cameron County exceeds the national average of 2.4 beds per 1,000 people (see DHR application, pg. 13 of Appendix C). To the extent that DHR has shown any need for any expansion, it would be a need for expanded capacity at its current location in Hidalgo County. And, in fact, CMS has already granted DHR’s request to add 551 operating rooms, procedure rooms, and beds under the “applicable hospital” exception to the expansion limitations for physician-owned hospitals,<sup>14</sup> but DHR has failed to follow through with a robust expansion of its on-campus capacity in Hidalgo County. In obtaining the “applicable bed” expansion exception, DHR presented HCRIS data indicating that DHR has an average bed occupancy rate that is greater than the statewide bed occupancy rate. At present, DHR has 363 acute licensed beds (despite CMS’ grant of its “applicable hospital” exception

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location be operated under the same license as the main provider where states license remote locations, but DHR is seeking to bypass State licensing requirements through a waiver process.

<sup>12</sup> 2020 DSH Qualification Workbook, released by the Texas Health and Human Services Committee (HHSC) on April 7, 2020; 2021 DSH Qualification Workbook, released by the HHSC on June 2, 2021

<sup>13</sup> *Id.*

<sup>14</sup> 80 Fed. Reg. 55851 (Sep. 17, 2015).

request) but operated at 80.02%, 85.71%, and 83.90% occupancy over the three most recent fiscal years.<sup>15</sup>

Despite the data showing high utilization in Hidalgo County, DHR is seeking to instead expand in a different community that is already well served by existing providers. There are currently two general acute care hospitals in Brownsville: Valley Baptist Medical Center – Brownsville (VBMC with 240 acute licensed beds) and Valley Regional Medical Center (VRMC with 214 acute licensed beds). Over the past three fiscal years, the percentage occupancy at these two facilities has ranged between 46.06% (VBMC in 2019) and 66.02% (VRMC in 2021), indicating that additional capacity is not needed in Brownsville. In addition, as explained below, VRMC has consistently had a higher percentage of Medicaid discharges as compared to DHR, indicating that Medicaid beneficiaries are already well served in Brownsville.

***The Proposed Brownsville Campus is Unlikely to Operate as a High Medicaid Facility.*** Medicaid beneficiaries in Brownsville, Texas are already served by several Cameron County hospitals. In particular, the percent of total VRMC hospital discharges that were Medicaid discharges was 46.188% in 2021, 50.145% in 2020, and 50.522% in 2019. These numbers exceed DHR’s Medicaid percentages in these years (41.672%, 37.431%, and 46.176%, respectively). ***The statutory criteria for a high Medicaid facility focus on the percent of Medicaid admissions “in the county in which the hospital is located,”<sup>16</sup> but it is not clear that Congress (or CMS) anticipated the high Medicaid facility expansion exception being used to create a new hospital campus over 50 miles away in another county where existing hospitals already exceed the expanding provider’s percent of Medicaid admissions.*** CMS should therefore use its discretion to consider the Medicaid discharge percentages in Cameron County in evaluating the public interests at play. Because DHR serves a lower percentage of Medicaid beneficiaries in Hidalgo County compared to VRMC in Cameron County, it appears unlikely that DHR would operate a high Medicaid facility in Cameron County if it expanded there.

Along similar lines, DHR provides relatively low levels of uncompensated care compared to Brownsville and Edinburg hospitals. DHR’s uncompensated care cost as a percentage of operating expenses has been consistently less than half of the uncompensated care percentages for the two existing Brownsville hospitals (VBMC and VRMC) and also significantly less than the other large hospital based in Edinburg (South Texas Health System):<sup>17</sup>

Year	DHR	Valley Baptist Medical Center Brownsville	Valley Regional Medical Center	South Texas Health System
2021	4.62%	9.22%	11.80%	14.09%
2020	3.83%	12.69%	13.72%	14.73%
2019	5.43%	13.57%	12.86%	8.67%
2018	3.27%	12.75%	12.01%	11.40%

<sup>15</sup> HCRIS data, available at <https://www.cms.gov/Research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/hospital-2010-form>.

<sup>16</sup> Social Security Act § 1877(i)(3)(F)(ii).

<sup>17</sup> HCRIS data, available at <https://www.cms.gov/Research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/hospital-2010-form>.

Careful consideration of this data is appropriate because the statute does not set forth a process for revoking an expansion exception if a physician-owned hospital, after expanding to a new community, exploits the whole-hospital exception to direct cherry-picked physician-investor referrals of lucrative patient populations to its facilities, compromising the payer and case mix at other area general acute care hospitals.

***DHR's Proposal to Transfer Patients to its Edinburg Campus Raises Significant Safety Concerns.*** In its request for a waiver of the 30-mile limitation on new hospital locations under Texas Law, DHR indicated that if a patient requires a transfer, that patient would be transferred to the DHR parent hospital in Edinburg (see page 6 of Appendix C). This would mean that patients requiring transfer would travel over 50 miles rather than receiving care at another Brownsville acute care facility. The proposed patient transfer process creates significant safety concerns that are wholly unnecessary considering the services and facilities in Brownsville and Cameron County. In addition, the high occupancy rate at DHR raises additional concerns as patients will be transferred from an area with more moderate hospital utilization and lower occupancy rates (occupancy rates in Brownsville hospitals have ranged between 46.06% and 66.02% over the past three years) to a high-occupancy facility (over 80% occupancy at DHR from 2019 through 2021).<sup>18</sup>

### ***3. The ACA's Limitations on the Whole Hospital Exception Provide Crucial Programmatic Protections that Warrant Rejecting DHR's Request***

Under the ACA amendments to the physician self-referral law, the owners of DHR cannot build a new hospital and then make referrals to that hospital. Instead, DHR's only option to expand physician-ownership into a new market is to cobble together a high Medicaid facility expansion exception with a Texas licensing thereby exploiting the law and regulation as amended in December 2020 by leveraging its grandfathered status under the ACA. There is no indication that Congress intended the high Medicaid facility exception to be used to permit such an expansion of a physician-owned hospital into a new and distinct market. Rather, with the high Medicaid facility and applicable hospital exceptions, Congress simply recognized that expansion exceptions may be necessary to protect access to care among Medicaid and low-income individuals in certain communities. But, here, the expansion request overlooks local needs in DHR's own community and instead exploits local circumstances to expand into a new market.

In short, the extraordinary facts presented by DHR make clear that it is inappropriate for CMS to approve a physician-owned hospital expansion simply because the three high Medicaid facility criteria are met. The creation of a new physician-owned hospital in Brownsville risks distorting the hospital market, skewing hospital payer and case mix, and raising the costs of health care in the area – the very reasons Congress enacted the POH prohibitions in the first place. In fact, the public discourse that ultimately prompted the ACA's prohibition opening and expanding physician-owned hospitals has its roots in Atul Gawande's seminal article, *The Cost*

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<sup>18</sup> HCRIS data, available at <https://www.cms.gov/Research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/hospital-2010-form>.

*Conundrum*, which highlighted the extraordinary cost of care at DHR.<sup>19</sup> CMS should therefore deny the request, and the AHA and FAH further urge CMS to repeal its December 2020 amendments to 42 C.F.R. § 411.362(c)(1), restoring the on-campus requirement for high Medicaid facility expansions.

The AHA and FAH appreciate the opportunity to submit these comments. If you have any questions, please contact us or have a member of your team contact Joanna Hiatt Kim, AHA Vice President for Payment Policy, at (202) 626-2340 or Steve Speil, FAH Executive Vice President, Policy, at (202) 624-1529.

Sincerely,



Stacey Hughes  
Executive Vice President  
American Hospital Association



Charles N. Kahn III  
President and CEO  
Federation of American Hospitals

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<sup>19</sup> Atul Gawande, *The Cost Conundrum—What a Texas Town Can Teach Us about Health Care*, NEW YORKER (June 1, 2009), available at <https://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum>.





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October 5, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***Re: CMS–1736–P, Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals Proposed Rule (Vol. 85, No. 156), August 12, 2020.***

Dear Administrator Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2021.

Below is a summary of our overarching concerns and comments:

***340B Drug Pricing Program. The AHA continues its steadfast opposition to any payment cuts made to 340B hospitals. We do not believe HHS has the legal authority to punitively target 340B hospitals in this manner.*** Since 2017, HHS has proposed yearly Medicare OPPS payment cuts for drugs purchased under the 340B program at a rate of Average Sales Price (ASP) minus 22.5% from the original payment rate of ASP plus 6%, representing an almost 30% payment cut. This policy eliminated approximately \$1.6 billion annually in payments to hospitals participating in the 340B program. In the CY 2021 OPPS proposed rule, HHS proposes a new payment rate, further reducing the payment for drugs purchased under the 340B program to ASP



minus 28.7%. This proposal is estimated to take an additional \$427 million from 340B hospitals and builds on flawed policy that has already resulted in devastating losses to 340B hospitals and their patients. **To this point, the AHA, along with other hospital associations and member hospitals, recently called on the full U.S. Court of Appeals for the District of Columbia Circuit to reconsider the July 31 non-unanimous decision by a three-judge panel that upheld the authority of HHS to cut 2018 and 2019 Medicare OPPS payments for 340B hospitals by nearly 30% per year. As 340B hospitals rise to meet the tremendous challenges resulting from the COVID-19 pandemic, the AHA asks HHS to immediately reverse this harmful policy and ensure these hospitals can continue to provide vital services to the patients and communities they serve.**

*Inpatient-only List.* **With regard to CMS's proposed changes to the inpatient-only (IPO) list, the AHA opposes eliminating the IPO list over a three-year period.** Given the depth and breadth of the more than 1,700 procedures on the IPO list, it would be premature and myopic to adopt such a policy. The IPO list was put into place to protect beneficiaries; many of its services are surgical and high risk. They are complicated and invasive procedures with the potential for multiple days in the hospital, an arduous rehabilitation and recovery period, and which require the care and coordinated services provided in the inpatient setting of a hospital. In addition, we are concerned about the financial and administrative burden of the elimination of IPO list at the same time that hospitals are grappling with the COVID-19 pandemic. It would be unconscionable to finalize this policy when the financial impact of the COVID-19 public health emergency (PHE) has already been devastating for hospitals – and there still remains an uncertain future as to the path of the pandemic. **We recommend that CMS continue with its standard process for removing procedures from the IPO list. The agency could enhance determinations about individual procedures that could be safely removed by setting general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities and social support, and other factors relevant to positive patient outcomes.**

*ASC Covered Procedures List.* **The AHA strongly opposes both of CMS's alternative proposals regarding the ASC covered procedures list (CPL). They would substantially weaken the agency's process and regulatory exclusion criteria for determining whether surgical procedures may be added to the ASC-CPL. Both alternatives would result in far more and higher risk surgical procedures being covered; the AHA is concerned that this could negatively impact Medicare beneficiary safety and quality of care.** As has been demonstrated in recent years, the existing ASC regulatory criteria have supported the ability of ASCs to safely furnish an expanding range of surgical procedures as innovations in surgical care occur. However, because ASCs are not subject to the same level of regulatory oversight as hospitals and are not equipped to manage emergencies that require lifesaving hospital inpatient capabilities, keeping the ASC general exclusion criteria in place prevent surgical procedures that pose significant threats to beneficiary safety

and quality of care from being performed in ASCs. **In addition, the AHA strongly opposes CMS's proposal, under Alternative 2, to add 270 surgery or surgery-like codes to the ASC-CPL that it believes would meet the proposed revised criteria for 2021.** CMS did not provide any rationale that these procedures meet even the general regulatory standards for adding ASC-covered surgical procedures.

**Furthermore, although the AHA strongly opposes the proposed changes to the ASC-CPL process and criteria, if CMS were to nevertheless finalize either alternative, we urge the agency to work with clinical experts and other stakeholders to make appropriate changes to the ASC Conditions for Coverage (CfC) in response to the expanded range of higher risk services that would be covered in the ASC setting. Particularly, we recommend restoring the CfC requirements removed in 2019 requiring written hospital transfer agreements or physician admitting privileges at a hospital.**

*Hospital Overall Star Ratings.* **The AHA applauds CMS for proposing changes to hospital overall star ratings.** The changes attempt to address the serious questions AHA and others have raised about the transparency and fairness of the ratings. We strongly urge CMS to adopt its proposals to discontinue the use of the latent variable modeling approach to measure group scores, and to stratify hospital readmissions measure group scores by the proportion of dual-eligible patients. We also agree with the intent behind CMS's proposal to peer group hospitals by the number of reported measure groups, though we encourage the agency to continue exploring additional alternative approaches.

*Physician-owned Hospitals.* **The AHA strongly opposes CMS's proposals to remove certain restrictions on the expansion of physician-owned hospitals (POHs) that qualify as high-Medicaid facilities.** These proposals would significantly undermine the statutory provisions in the Stark law and Affordable Care Act that protect federal health care programs from the inherent conflict of interest created when physicians self-refer their patients. Such a change flouts decades of evidence, including from as recently as August, that POHs cherry-pick healthy patients, provide few emergency services or uncompensated care, and are penalized for unnecessary readmissions at 10 times the rate of non-POHs, all while maintaining significantly higher operating margins than non-POHs. In fact, CMS's proposals to ease expansion for high-Medicaid facility POHs would allow expansion of facilities that actually have extremely low-Medicaid discharge percentages when compared with hospitals in surrounding counties. **These proposals pose grave risk to the stability and integrity of patient care and should not be finalized.**

With regard to other proposed policies included in the rule, the AHA:

- Recommends that CMS reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted provider-based departments;
- Recommends that CMS revise the medical review exemption policy for services removed from the IPO list. Doing so would provide ongoing deference to the physician's judgement about the appropriate site of care, and thereby exempt

providers from site-of-service claims denials until there is evidence showing that a removed service is more commonly performed on an outpatient basis.

- Strongly supports CMS's proposal to permanently establish general supervision as the minimum required supervision level for all non-surgical extended duration therapeutic services;
- Supports CMS's proposal that direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services could include the virtual presence of the physician through audio/video real-time communications technology. However, we urge CMS not to finalize a clarification that would require the physician's "real-time presence throughout the performance of the procedure," rather than "immediate availability" using this technology;
- Urges CMS to continue the "Hospital without Walls" flexibilities to the greatest extent possible; and
- Continues to oppose the OPPTS prior authorization program, as well as its expansion to two new categories of service, as the policy is contrary to law and arbitrary and capricious.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director for policy, at [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Ashley B. Thompson  
Senior Vice President  
Public Policy Analysis and Development

**American Hospital Association (AHA)  
Detailed Comments on the Outpatient Prospective Payment  
System (OPPS) and Ambulatory Surgical Center (ASC)  
Payment System Proposed Rule for Calendar Year (CY) 2021**

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## **OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS**

For CY 2019, citing “unnecessary” increases in the volume of outpatient clinic visits in hospital provider-based departments (PBDs) allegedly due to payment differentials driving the site-of-service decision, CMS finalized a policy to pay for clinic visits furnished in excepted off-campus PBDs at the same rate they are paid in non-excepted off-campus PBDs. Specifically, in the CY 2019 final rule, CMS adopted a policy to pay for excepted clinic visit services at the physician fee schedule (PFS)-equivalent payment rate of 40% of the OPPS payment amount. The agency, however, phased-in the application of this policy over two years. That is, in CY 2019, half of the reduction was applied, meaning that in 2019, excepted off-campus PBDs are paid 70% of the OPPS rate for excepted off-campus clinic visits services and in CY 2020, CMS completed the phase-in to pay for clinic visit services furnished in excepted off-campus PBDs at the payment rate of 40% of the OPPS payment amount. This policy was implemented in a non-budget neutral manner, which the agency estimated would result in a CY 2020 reduction of \$800 million in hospital payments under the OPPS.

For CY 2021, CMS would continue to pay for the hospital outpatient clinic visit services in off-campus excepted PBDs at 40% of the OPPS payment amount. **AHA continues to believe that the payment cut for hospital outpatient clinic visits threatens access to care, especially in rural and other vulnerable communities, and that CMS has undermined clear congressional intent and exceeded its legal authority.** The AHA is seeking a rehearing by the full U.S. Court of Appeals for the District of Columbia Circuit of the recent decision overturning a lower court’s ruling in favor of AHA and hospitals that invalidated HHS’s policy finalized in the CY 2019 rule to pay for clinic visit services in excepted PBDs at the “PFS-equivalent” payment rate of 40% of the OPPS payment amount. For further discussion on this topic, please see the [AHA’s CY 2020 OPPS/ASC proposed rule comment letter](#) and the [AHA’s Petition for Panel Rehearing or Rehearing En Banc](#).

The Growth in Outpatient Volume and Expenditures is not “Unnecessary”. **This policy not only runs afoul of the law but also relies on the most cursory of analyses and policy rationales.** In its CY 2019 and 2020 rulemaking, CMS finalized its phased-in policy implementing a 60% cut in payment for a clinic visit, an essential hospital outpatient service, without presenting any of its own data analysis on:

- Clinic visit volume;
- Clinic visit expenditures;
- The “unnecessary” nature of clinic visit volume or expenditures;
- The “shifting” volume of clinic visits from physician offices to excepted off-campus PBDs due to payment differentials; or
- How a reduction in payment for the hospital outpatient clinic visit is a “method” that would lead to a reduction in the volume of “unnecessary” services in excepted off-campus PBDs.

Indeed, this complete lack of data, analysis and evidence did not go unnoticed. At the Aug. 19, 2019 meeting of CMS's Advisory Panel on Hospital Outpatient Payment, members expressed concern that CMS had not followed through on its 2018 recommendation that the agency *not implement* the proposal for reduction in payment for outpatient clinic visits and instead study the matter to better understand the reasons for increased utilization of outpatient services. Indicating their continued concern about the lack of evidence to support CMS's clinic visit payment reduction and the policies' possible impacts on access to care, the Panel voted unanimously to recommend that CMS freeze the payment policy for off-campus clinic visits at CY 2019 rates and evaluate whether beneficiary access has been compromised and whether the volume of outpatient services has decreased.

**Blaming increases in OPPS expenditures on the “unnecessary” shifting of services from physician offices to PBDs in response to payment differentials ignores the many factors outside of hospitals’ control that also result in increases in OPPS volume and expenditures.** This includes such things, as changes in patient demographics and clinical needs, technological advances, changing economic incentives from CMS and other payers, the impact of other Medicare policies that are intended to increase the volume of services in PBDs, drug price inflation, or the fact that physicians often refer Medicare beneficiaries to HOPDs for services they do not provide in their offices.

We describe below some of the many factors that may be contributing to increases in OPPS volume.

*Medicare Policies that Shift Care to PBDs.* Medicare has many policies that are intended to promote greater use of outpatient services or that otherwise incentivize increases in outpatient services. By definition, increases in volume and expenditures in PBDs that result from these policies cannot be seen to be “unnecessary.” Yet, CMS did nothing to analyze the effect of these policies, such as:

- Readmissions program;
- Value-based care;
- Two-midnight policy;
- Packaging of Clinical laboratory Services into the OPPS; and
- Changes to the inpatient-only (IPO) list.

*Factors Outside of Hospitals’ Control that Increase OPPS Volume and Expenditures.* There are many broader health care trends that contribute to the increase in OPPS expenditures, all of which are outside of hospitals’ control. We highlight a few below. Again, by definition, increases in volume and expenditures resulting from these trends cannot be considered “unnecessary,” although CMS did not attempt to analyze their effect.

- Drug Price Inflation. In the CY 2019 OPPS proposed rule, CMS included a table which described the growth in expenditures under OPPS from CY 2010 through CY 2019. The agency used these data to justify its proposed policy intended to address “unnecessary” growth in volume in the OPPS. However, a footnote in the table indicated that the growth rates shown included Medicare Part B drug expenditures. Drug price inflation is a key factor contributing to the growth in OPPS expenditures that is entirely outside of the control of hospitals. Indeed, HHS, the Medicare Payment Advisory Commission (MedPAC) and others have expressed concern about the rapid growth in drug expenditures. According to MedPAC, “The largest source of OPPS spending growth has been Part B drugs, which include those that have pass-through status (drugs that are new to the market) and those that are not pass-through but are separately payable under the OPPS. From 2012 to 2018, OPPS spending for these drugs increased from \$6.0 billion to \$12.9 billion, an increase of 115% (13.6% per year, on average) ... The growth in spending on Part B drugs is due to price increases, increased use of existing drugs, and, to a lesser extent, the introduction of new, expensive cancer drugs.”<sup>1</sup>

In more recent years, per-capita spending on drugs in the United States has grown significantly, with year-over-year growth reaching historically high levels in 2014 (12.4%) and 2015 (8.9%).<sup>2</sup> This growth was driven primarily by changes in drug prices, including both higher launch prices and annual price increases, not utilization.<sup>3</sup> In recent years, growth in spending on prescription drugs has slowed from those historic levels, yet the impact of continued price increases is compounded by the simple fact that each annual increase builds on the previous year’s increase. For example, in 2017 increases continued for drugs like mitomycin, which is used to treat cancer, and hydromorphone, an injectable opioid. Mitomycin nearly doubled, increasing by 99 percent, and hydromorphone increased by 107 percent. As prices have continued to increase for many drugs like mitomycin, ongoing manufacturing shortages of many prescription drugs have threatened patient access to care.<sup>4</sup>

- Physician Referrals. Some of the increase in outpatient expenditures under the OPPS is the result of independently practicing physicians referring beneficiaries to the PBD for services that the physician does not deliver in his or her office, such as wound care or Coumadin clinic services. These types of referrals are clearly not the result of an “unnecessary” shifting of services from a lower cost to a higher cost setting because the services rendered by the PBD are not available in physician offices.

Continued Cuts to Hospital Reimbursements for Clinic Visits are Excessive and Harmful, Especially during the Global COVID-19 Pandemic. As noted above, CMS

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<sup>1</sup> MedPAC Report to the Congress: Medicare Payment Policy, March 2020.

<sup>2</sup> The National Health Expenditure Accounts.

<sup>3</sup> U.S. Department of Labor, U.S. Bureau of Labor Statistics. PPI Detailed Report: December 2017.

<sup>4</sup> NORC at the University of Chicago, “Recent Trends in Hospital Drug Spending and Manufacturer Shortages”, Jan. 1, 2019.



proposes to continue to impose the 60% cut in payment for clinic visits furnished in excepted off-campus PBDs. **Continuing these cuts to outpatient payment for clinic visits, particularly in light of the devastating impact that the COVID-19 pandemic has had on hospital and health system financial health, would be excessive and harmful to patients and communities.**

Hospitals and health systems are expected to lose a minimum of \$120.5 billion from July through December 2020 as a result of the pandemic, due in large part to lower patient volumes, according to an AHA report.<sup>5</sup> This is an average of \$20.1 billion per month. These estimates are in addition to the \$202.6 billion in losses the AHA estimated hospitals incurred from March through June 2020<sup>6</sup>. This brings the total estimated pandemic-related losses for the nation's hospitals and health systems to at least \$323.1 billion in 2020. While, to date, the impact of COVID-19 has been significant, even with federal emergency funding, the financial damage is likely to continue. Adding to this financial impact is the unpredictability of COVID-19's trajectory, and the pace and degree of patients' return to hospitals. In the face of greatly eroded volume and revenue, and a long recovery period, many hospitals are confronted with extremely difficult choices about their paths forward as vital community assets. Now more than ever, hospitals will need support from government for what is likely to be a highly challenging environment even as COVID-19 cases diminish.

**Continuing to impose a 60% cut on clinic visit services in 2021, on top of the dire financial impacts on U.S. hospitals and health systems due to COVID-19, would greatly endanger the critical role that HOPDs play in their communities, including providing convenient access to care for the most vulnerable and medically complex beneficiaries.**

Specifically, among all Medicare beneficiaries, relative to patients seen in physician offices, patients seen in HOPDs:

- Have more severe chronic conditions;
- Have higher prior utilization of hospitals and emergency departments (ED);
- Are more likely to live in low-income areas;
- Are 1.7 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.3 times more likely to be non-white;
- Are 1.6 times more likely to be under age 65 and, therefore, eligible for Medicare based on disability, end-stage renal disease or amyotrophic lateral sclerosis; and
- Are 1.1 times more likely to be over 85 years old.<sup>7</sup>

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<sup>5</sup> <https://www.aha.org/system/files/media/file/2020/06/aha-covid19-financial-impact-report.pdf>.

<sup>6</sup> <https://www.aha.org/system/files/media/file/2020/05/aha-covid19-financial-impact-0520-FINAL.pdf>.

<sup>7</sup> Source: KNG Health Consulting, LLC analysis of 2011-2019 Medicare Inpatient, Outpatient, and Carrier Standard Analytical Files and Denominator files.

Among Medicare beneficiaries with cancer, the differences in the types of patients seen in HOPDs compared to physician offices is even starker. For example, relative to cancer patients seen in physician offices, cancer patients seen in HOPDs not only have more severe chronic conditions, higher prior utilization of hospitals and EDs, and higher likelihood of residing in low-income areas, but also:

- Are 2.2 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.8 times more likely to be non-white; and
- Are 2.4 times more likely to be under age 65 and, therefore, eligible for Medicare based on disability, end-stage renal disease or amyotrophic lateral sclerosis.<sup>8</sup>

Further, according to the FY 2018 Medicare cost report data, Medicare margins for outpatient services were negative 13.8% in 2018. Overall Medicare margins were negative 9.3% in 2018, with a negative 11% margin predicted for 2019.<sup>9,10</sup> Of note, even “efficient” hospitals had a margin of negative 2% in 2018, according to MedPAC.<sup>11</sup> **The site-neutral payment policies implemented by CMS for 2018 and beyond will reduce these margins further. Moreover, according to a recent analysis of the impact of the COVID-19 pandemic on hospitals, prepared by Kaufman, Hall & Associates LLC<sup>12</sup> and released by AHA, even with the Coronavirus Aid, Relief, and Economic Security (CARES) Act funding, hospital operating margins are expected to drop 5.5 percentage points – to negative 2% in the second quarter of 2020.** Before COVID-19, the median hospital operating margin was a modest 3.5%. For any organization, a positive operating margin is essential for long-term survival.

We are concerned that continued Medicare site-neutral payment reductions, together with the devastating impacts of COVID-19, will threaten beneficiary access to critical hospital-based “safety-net” services and undermine the ability of hospitals to adequately fund their 24/7 emergency standby capacity. **For better or worse, the hospital safety-net and emergency stand-by role are funded through the provision of all outpatient services. If CMS continues to erode this funding, so too will these critical services be eroded.**

In fact, this erosion is already occurring, due in no small part to CMS’s policies. As spurred by the steady decline in Medicare margins over the past two decades, and as documented by the North Carolina Rural Health Research Program, 132 rural hospitals have closed since 2010, 15 of them in 2020 thus far. While MedPAC and others dismiss these closures by noting that the hospitals were “small” or “near other facilities,” the concern remains that these very vulnerable rural hospitals are the “canaries in the coal

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<sup>8</sup> Ibid.

<sup>9</sup> MedPAC Report to the Congress: Medicare Payment Policy. March 2020.

<sup>10</sup> MedPAC Report to the Congress: Medicare Payment Policy. March 2019.

<sup>11</sup> MedPAC Report to the Congress: Medicare Payment Policy. March 2020.

<sup>12</sup> [https://www.aha.org/system/files/media/file/2020/07/KH-COVID-Hospital-Financial-Health\\_FINAL.pdf](https://www.aha.org/system/files/media/file/2020/07/KH-COVID-Hospital-Financial-Health_FINAL.pdf).

mine.” They serve as the initial indicators that we are beginning to reach a tipping point where private payers are no longer willing to fund, and hospitals can no longer sustain, operations on the cost-shift that such considerable Medicare underpayments, particularly those under OPPS, necessitate.

Site-neutral Policies are Based on Flawed Assumptions. Finally, the entire premise of CMS’s site-neutral policies is based on the flawed assumption that Medicare PFS payment rates are sustainable rates for physicians. However, the truth is much different. AHA members tell us that when they acquire independent physician practices, it occurs because the physicians have reached a tipping point – their practices are failing due to poor payer mix, increasing Medicare and Medicaid regulatory burden, and declines in Medicare and Medicaid reimbursement. Instead of allowing these physician services to be lost to the community, or in communities where there are already health care deserts, hospitals purchase the practices in order to ensure continued access to these services.

**All of this discussion supports the conclusion that CMS should reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted PBDs.**

## **PAYMENTS FOR 340B**

HHS, through CMS, has relentlessly pursued payment policies designed to undermine the scope and intent of the 340B Drug Pricing Program. Since 2017, HHS has proposed yearly Medicare OPPS payment cuts for drugs purchased under the 340B program at a rate of Average Sales Price (ASP) minus 22.5%, representing an almost 30% payment cut from the original payment rate of ASP plus 6%. This policy eliminated approximately \$1.6 billion annually in payments to most hospitals participating in the 340B program.

For more than 25 years, the 340B program has been critical for hospitals to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services. Hospitals rely on these savings to provide important services and resources that they may otherwise be unable to provide, many of which are targeted to low-income and otherwise vulnerable communities. These savings have proved especially important as 340B hospitals are also on the front lines of the COVID-19 PHE. We, therefore, continue to argue, as documented in our court filings, that HHS does not have the legal authority to punitively target 340B hospitals in this manner. **On Sept. 14, the AHA, Association of American Medical Colleges, America's Essential Hospitals, and three hospital plaintiffs called on the full U.S. Court of Appeals for the District of Columbia Circuit to reconsider the July 31 non-unanimous decision by a three-judge panel that upheld the authority of HHS to cut 2018 and 2019 Medicare OPPS payments for 340B hospitals by nearly 30% per year.**<sup>13</sup>

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<sup>13</sup> AHA et al vs Azar USCA Case #19-5048 Document #1861298 (US Court of Appeals for the District of Columbia)  
<https://www.aha.org/legal-documents/2020-09-14-hospital-groups-petition-rehearing-re-340-b-payment-reductions-sept-14>.

In this CY 2021 OPPS proposed rule, HHS proposes to further reduce payments for drugs purchased under the 340B program to ASP minus 28.7%. This proposal is estimated to cut an additional \$427 million from 340B hospitals. HHS is basing this new payment rate on results from CMS's Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs, which was inadequate and incomplete. In addition, the new proposal continues to build on flawed policy that has already resulted in devastating losses to 340B hospitals and their patients. **Therefore, the AHA continues its unshakeable opposition to any payment cuts made to 340B hospitals and asks HHS to immediately reverse this harmful policy and ensure these hospitals can continue to provide vital services for the patients and communities they serve.**

340B Payment Rate Approaches. HHS, in this proposed rule, puts forward a new approach to pay certain 340B hospitals for covered outpatient drugs purchased through the 340B program. That new approach would result in a net payment rate of ASP minus 28.7%.<sup>14</sup> Alternatively, HHS offers to continue the current payment rate of ASP minus 22.5% for 340B hospitals. The department requests comment on retaining the current payment policy in light of the July 31 favorable Appeals Court decision upholding the departments' authority to cut 340B hospitals by nearly 30% annually.<sup>15</sup> However, this choice that HHS has offered to 340B hospitals is a classic Cornelian Dilemma, wherein hospitals are being asked to choose between two courses of action, both of which will have a detrimental effect.<sup>16</sup> **For 340B hospitals, there can be no other choice but for HHS to reverse this harmful and punitive policy. Therefore, the AHA opposes ANY AND ALL proposals that seek to reduce payment to 340B hospitals.**

HHS bases the new proposed payment rate of ASP minus 28.7% on the results of CMS's Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs, which was issued in the spring of 2020. It is important to note that the survey was issued during the height of the COVID-19 PHE while 340B hospitals were struggling to marshal critical resources to respond to the pandemic. All hospitals that are paid under the OPPS and participate in the 340B program were surveyed, including rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals (which are currently exempt from the Medicare 340B payment rate adjustment). A central point in the litigation that AHA and others have brought forth is HHS's failure to collect the required actual acquisition cost data to establish a 340B-specific payment rate. As noted by the Circuit Judge Pillard of the Appeals Court of the District of Columbia Circuit, HHS can only pursue a different payment policy for a distinct hospital group through the robust, hospital-specific data effort specified by the law.<sup>17</sup> Further, the

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<sup>14</sup> CMS arrived at the net payment rate of ASP minus 28.7 % by starting at ASP minus 34.7%, plus an add-on of 6% of the product's ASP, for a net payment rate of ASP minus 28.7%. This proposed new payment rate extends to 340B-acquired drugs furnished in non-grandfathered (non-excepted) off-campus provider-based departments and applies to biosimilar drugs and other drugs without an ASP purchased through the 340B program.

<sup>15</sup> [https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/\\$file/19-5048-1854504.pdf](https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf).

<sup>16</sup> *Le Cid*, Pierre Corneille, 1637, performed at the Theatre du Marais, Paris.

<sup>17</sup> [https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/\\$file/19-5048-1854504.pdf](https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf).

statute requires any such survey to contain a large sample of hospitals that would yield statistically significant data. **HHS's data collection effort falls short of these standards set forth by Congress in several ways.**

First, as AHA noted in our March comments to HHS on the survey, the survey design and approach did not meet the statutory requirements when it specified that only 340B hospitals were required to complete the survey.<sup>18</sup> It is worth repeating that under the statute, in establishing reimbursement rates for outpatient drugs, HHS must either use average acquisition costs based on a survey that meets the requirements of the statute (subclause I of section 1395l(t)(14)(iii)) or average price based on various statutory provisions (subclause II of section 1395l(t)(14)(iii)). HHS may not use subclause I for some hospitals and subclause II for others, and thus it may not limit the survey to a subset of hospitals. Congress in (t)(14)(C)(ii) of the statute directs HHS to collect "hospital acquisition cost for each specified covered outpatient drug for use in setting the payments rates...." Nowhere in the statute does Congress give HHS the authority to collect acquisition cost data from only a specific subset of all hospitals. While Congress does state in (t)(14)(A)(iii) that CMS could vary hospital OPPS payment by hospital group – based on the data gleaned from the hospital acquisition cost survey – the potential variation is premised on the use of the authority in subclause I to establish the rate for all hospitals and thus the survey must include all hospitals, not just a subset of hospitals. In other words, for purposes of surveying hospitals, Congress did not distinguish between hospitals paid under OPPS based on their 340B status and those that are not and doing so is, therefore, a clear violation of the statute.

Second, the statute governing the provision of such a survey requires that the survey data meet certain requirements. Under 42 U.S.C. Sec.1395l(t)(14)(D)(iii), the survey must "...have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug."<sup>19</sup> HHS noted only 7% of hospitals that received the survey responded with actual acquisition cost data. Of the remaining hospitals surveyed, 38% did not respond and an additional 55% opted for a "quick survey" where CMS used 340B ceiling prices maintained by the Health Resources and Service Administration (HRSA) as a proxy for actual drug acquisition costs. With such a low response rate, it is apparent that HHS was unable to gain enough data to yield a statistically significant estimate of average hospital acquisition cost for each specified covered outpatient drug. Further, the acquisition data collected in the survey only reflected data from the fourth quarter of 2018 and the first quarter of 2019. Given that drug acquisition costs can vary significantly quarter to quarter due to rapid fluctuations in drug prices, the limited data used to set payment rates may not represent actual acquisition costs in a meaningful way. This could result in a scenario where a drug increases significantly in price, where the payment rate for that drug is below the 340B ceiling price, such that a hospital would incur losses for use of that drug. Ultimately, it is clear that HHS did not meet the basic

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<sup>18</sup> <https://www.aha.org/system/files/media/file/2020/03/cms-survey-hospitals-participate-340b-drug-pricing-program-3-9-2020.pdf>.

<sup>19</sup> <https://www.law.cornell.edu/uscode/text/42/1395l>.



statutory requirements for use of such a survey in setting payment rates, as outlined above.

Finally, in the proposed rule, HHS noted that it was neither necessary nor appropriate to burden non-340B hospitals with a drug acquisition cost survey because it believed that ASP plus 6% is a reasonable proxy for hospital acquisition and overhead costs for separately payable drugs. However, as Judge Pillard further notes in her dissenting opinion, “But concerns about the program’s effects, and confidence in the agency’s care in using data other than those the statute requires, cannot somehow authorize the agency to do what the statute does not.”<sup>20</sup> **For the reasons outlined above, the AHA strongly believes that HHS’s survey used to develop this new payment approach does not meet the statutory requirements and may not be relied upon in establishing the payment rate.**

Failure to Provide Sufficient Analysis for the Continuation of the 340B Payment Policy.

In addition to the concerns cited above, HHS has failed to provide any level of transparency or sufficient access to data, methodology or analysis to allow the public to assess and replicate the proposed CY 2021 340B payment policy. AHA has raised similar concerns in prior proposed OPPS payment rules.<sup>21</sup> In fact, there has been no indication that CMS has taken into account changes in which hospitals are actively participating in the program or changes in utilization and volume since CMS first proposed changes to 340B payment policy in 2017. In addition, it appears that CMS did not conduct any analysis of the impact of the prior year reimbursement changes for the drugs acquired under the 340B program for the affected hospitals as it prepared the CY 2021 OPPS proposed rule. Although HHS finalized the 340B policy as budget neutral in prior years, the agency has provided no evidence in the CY 2021 proposed rule that it met budget neutrality requirements. No other conclusion can be made except that HHS did not accurately and effectively ensure the budget neutrality of this policy. **On this point, the AHA recommends that, if HHS is allowed to continue the 340B payment policy, it should annually ensure that it remains budget neutral by recalculating the policy’s impact to make certain the conversion factor is properly adjusted.**

This approach is consistent with other budget-neutral policies included in OPPS, such as wage index, outliers, rural SCH adjustment, and cancer hospital adjustment, for which adjustments are analyzed and made annually via the OPPS conversion factor.

In conclusion, payment cuts of the magnitude that HHS proposes directly contravene the intent of the 340B program and will only result in the loss of resources and services at the worst possible time for these hospitals and the patients and vulnerable communities they serve. While the AHA supports the goal of bringing down drug prices for Americans, reducing payments to 340B hospitals do nothing to address the skyrocketing costs of pharmaceuticals. Therefore, the AHA continues its call on HHS to

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<sup>20</sup> [https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/\\$file/19-5048-1854504.pdf](https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf).

<sup>21</sup> <https://www.aha.org/news/headline/2018-09-24-aha-comments-oppsasc-proposed-rule-cy-2019>.

end this flawed policy and restore payments to 340B hospitals and to the patients and communities they serve.

## **PROPOSED CHANGES TO THE INPATIENT-ONLY LIST**

The IPO list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting. This is due to the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. Currently, the IPO list includes approximately 1,740 services.

CMS proposes to eliminate the IPO list over the three-year period, 2021 through 2024. For 2021, it would remove 266 musculoskeletal services from the list. In its discussion, CMS notes that it believes physicians should use clinical judgment, together with consideration of the beneficiary's specific needs, to select an inpatient or outpatient setting for care.

**The AHA strongly urges CMS not to finalize its proposal to eliminate the IPO list over three years.** The IPO list was put into place to protect beneficiaries. Many of its services are surgical procedures that are high risk – complicated and invasive procedures with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period, and which require the care and coordinated services provided in the inpatient setting of a hospital. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which could make these procedures even more complicated and risky if furnished in outpatient settings.

**The appropriate setting for procedures should be determined with a focus on patient safety and peer-reviewed evidence. However, CMS is proposing to remove certain procedures that do not have data to support the appropriateness of their performance in the outpatient setting.** For instance, there are some services on the IPO list that may never be appropriate to furnish in an outpatient setting and certainly should not be removed from the list within the next three years. These include, for example:

- CPT code 33935 Transplantation heart/lung;
- CPT 32853 Lung transplant double;
- CPT code 19306 Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation); and
- CPT code 3352 Coronary artery bypass, using venous graft(s) and arterial graft(s), six or more.

These services, as well as many others among the more than 1,700 services on the IPO list, could not be performed safely in hospital outpatient settings because of the

complex and high risk nature of the procedure and the fact that they require far more than 24 hours of postoperative recovery and monitoring time before the patient could be safely discharged.

We also are concerned that, even among the 266 musculoskeletal services proposed for removal in CY 2021, there are procedures without adequate data to support the appropriateness of their performance in the outpatient setting. According to the American Association of Orthopaedic Surgeons (AAOS), “Finalizing this policy as proposed will mean that complicated procedures from major trauma, such as pelvic, acetabulum, hip and fragility fractures and amputation that are mostly done with heavy inpatient monitoring, will be paid in the outpatient setting. AAOS experts believe that even with advances in medical practice, such procedures cannot be safely done in the outpatient setting currently.” The AHA agrees. There are many musculoskeletal procedures among the 266 which are high risk and would require more than 24 hours of recovery or monitoring time. For example, these include the facial reconstruction CPT codes 21141 through 21436 and the arm and forearm replantation surgeries CPT codes 20802 and 20805. Eliminating these procedures from the IPO list would pose serious risks and have negative quality of care implications for vulnerable Medicare patients.

**Given the depth and breadth of services that are the IPO list, as discussed above, it is premature to adopt a policy to eliminate the IPO list over three years.** Instead, CMS should continue with its standard process for removing procedures. It could enhance determinations about individual procedures that could be safely removed from the IPO list by setting general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities, social support, and other factors relevant to positive patient outcomes.

**Further, this proposal is premature because CMS does not have the claims, cost and other data that would be needed to appropriately determine into which ambulatory payment classifications (APCs) the procedures should be incorporated. It also does not have adequate data for creating new APCs to capture IPO list procedures.** With over 1,700 IPO services, grouping procedures into APCs and creating new APCs where necessary will be a huge undertaking. Three years is clearly not enough time to do so.

**In addition, we are concerned about the financial and administrative burden of the elimination of the IPO list over such a short period of time at the same time that hospitals are grappling with the COVID-19 pandemic.** That is, when a procedure is taken off the IPO list, it tends to be generally healthier Medicare beneficiaries, with shorter lengths of stay whose care migrates to the hospital outpatient department, leaving the sicker and more complex patients as inpatients. Eliminating the entire IPO list over three years will magnify this impact on hospital costs. Furthermore, in the experience of our members, when CMS removes procedures from the IPO list, commercial payers adopt this policy as well, but Medicare’s “option” for the outpatient setting becomes the commercial payer’s justification for making it the default location. **It**



**would be unconscionable to finalize this policy when the financial impact of the COVID-19 PHE has already been devastating for hospitals – and there still remains an uncertain future as to the path of the pandemic.**

## **MEDICAL REVIEW OF CERTAIN INPATIENT HOSPITAL ADMISSIONS UNDER MEDICARE PART A FOR CY 2021 AND SUBSEQUENT YEARS**

CMS proposes to continue the two-year exemption from site-of-service claim denials under Medicare Part A, eligibility for beneficiary and family-centered care quality improvement organizations referrals to Recovery Audit Contractors (RACs) for non-compliance with the two-midnight rule, and RAC reviews for “patient status” for services removed from the IPO list under the OPPIs in 2021 and subsequent years. However, given that many more services would be removed from the IPO list during the proposed transition, CMS is seeking comment on whether to retain or lengthen the two-year exemption.

**If CMS eliminates the IPO list despite the concerns expressed by the AHA and others, we recommend that it abide by its ongoing deference to the physician’s judgement on the appropriate site of care and exempt providers from site-of-service claims denials beyond the current two-year period.** Two years is not enough time for adequate evidence and research to be conducted to demonstrate that procedures removed from the IPO list can be performed safely for Medicare beneficiaries in hospital outpatient settings. **As such, we recommend that CMS extend the medical review exemption period until such evidence is widely available and there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis.**

## **CHANGES IN THE LEVEL OF SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES**

For CY 2020, CMS changed the minimum required level of supervision from direct supervision to general supervision for most hospital outpatient therapeutic services provided by hospitals and critical access hospitals (CAHs). The AHA strongly supported this change, as we have repeatedly urged CMS for such a solution to this critical issue for rural hospitals since it was put forth in 2010. However, some groups of services, including non-surgical extended duration therapeutic services (NSEDTS)<sup>22</sup> and pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation, were not subject to the change in the required supervision level; those services continue to have a minimum default level of supervision that is higher than general supervision.

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<sup>22</sup> NSEDTS describe services, such as chemotherapy infusion services, that have a significant monitoring component that can extend for a lengthy period of time, that are not surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level of NSEDTS currently is direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising practitioner.

On Mar. 31, CMS issued an interim final rule with comment period (IFC) that gives Medicare providers needed flexibilities to respond effectively to the COVID-19 pandemic. In the IFC, the agency adopted a policy to reduce, during the PHE, the level of supervision for NSEDTS to general supervision for the entire service, including the initiation portion of the service, for which CMS had previously required direct supervision. The agency also specified that, for the duration of the PHE, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services includes the virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

While these policies were adopted on an interim final basis for the duration of the PHE, in the CY 2021 proposed rule, CMS indicates that it believes that they are appropriate outside of the PHE and should apply permanently. Therefore, the agency proposes to adopt these policies for CY 2021 and beyond.

**The AHA strongly supports CMS's proposal to permanently establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after Jan. 1, 2021.** This would be consistent with the minimum required level of general supervision that currently applies for most other outpatient hospital therapeutic services and, as AHA has advocated for many years, will allow small and rural hospitals additional flexibility to provide these critical services in underserved locations.

We agree with CMS's reasoning in proposing this policy, including that:

- It would allow greater flexibility in providing these services and reduce provider burden, thus improving access to these services in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner (NPP);
- A minimum requirement for general supervision does not preclude hospitals from providing direct supervision for any part of a NSEDTS when the physicians or NPP ordering or administering the medical procedure decides that it is appropriate to do so; and
- There are other requirements that apply to hospitals and physicians and NPPs which would complement the general supervision requirements for NSEDTS and help ensure that the medical services Medicare patients receive are properly supervised, such as the hospital and CAH conditions of participation (CoPs) and state scope of practice laws.

**The AHA also supports, with one key reservation, CMS's proposal that for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac**

**rehabilitation services, the required direct supervision could include the virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician.** We agree that the policy to allow direct supervision provided by the virtual presence of the physician would continue to improve access for patients and reduce burden for providers after the end of the PHE.

**However, we are concerned about, and urge CMS not to finalize, its clarification that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure.** Requiring real-time presence throughout the procedure, rather than “immediate availability,” is inconsistent with the statutory and regulatory definition of “direct supervision.” It is, in fact, more akin to “personal supervision.” As included in current regulatory definitions of “direct supervision” as well as the statutory language that defines the required level of supervision for cardiac rehabilitation, pulmonary rehabilitation and intensive cardiac rehabilitation programs, “direct supervision” does not require the presence of the physician for the duration of the service; rather it requires only that the physician be “immediately available” to furnish assistance, as necessary, through the performance of the procedure.

That is, 42 CFR 410.28(e)(1), as updated by the IFR, defines direct supervision as:

“the physician must be *immediately available* to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room where the procedure is performed. During a Public Health Emergency, as defined in §400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.”

Further, Section 1861(eee)(2)(B) of the Social Security Act establishes that, for cardiac, intensive cardiac and pulmonary rehabilitation programs, “a physician is *immediately available* and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed.” This statutory requirement is very similar to the requirement for direct supervision.

Neither definition of the direct supervision for these services mandates more than the *immediate availability* of the physician throughout the service. However, CMS’s clarification is closer to the definition of personal supervision (42 CFR 410.32(b)(3)(iii)), which means that “the physician must be in attendance in the room during the performance of the procedure” – than direct supervision. A personal level of supervision is unnecessary for these services (which are only furnished to stable outpatients) and is

inconsistent with the statutory requirement of direct supervision for cardiac, pulmonary and intensive cardiac rehabilitation services.

**The AHA strongly urges CMS not to finalize this clarification but rather allow the supervising physician to be *immediately available* to furnish assistance and direction throughout the service using audio/video real-time communications technology.**

## **PROPOSED NEW CATEGORY OF LAB TESTS EXCLUDED FROM OPPS PACKAGING**

Under current CMS policy, most clinical diagnostic laboratory tests are packaged under the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. However, certain laboratory tests, including molecular pathology tests, remain separately payable under the Clinical Laboratory Fee Schedule (CLFS).

In the CY 2021 proposed rule, CMS proposes to exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests from the OPPS packaging policy and pay for them separately under the CLFS. The AHA agrees with CMS that cancer-related protein-based MAAAs – similar to molecular pathology tests – are relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient and are instead used to guide future treatment through surgical procedures or chemotherapeutic interventions. Treatments that are based on the results of cancer-related protein-based MAAAs are typically furnished after the patient is no longer in the hospital, in which case they are not tied to the same hospital outpatient encounter during which the specimen was collected.

**Therefore, the AHA supports CMS's proposal that protein-based MAAA tests to diagnose cancer should no longer be packaged into OPPS payment.**

## **SPECIMEN COLLECTION FOR COVID-19 TESTS**

As result of the COVID-19 PHE, CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [covid-19]), any specimen source). HCPCS code C9803 is assigned to APC 5731- Level 1 Minor Procedures for the duration of the COVID19 PHE, with a payment rate of \$22.98 for 2020. HCPCS code C9803 is conditionally packaged meaning that it will only be paid separately if it is the only service provided or it is billed with a clinical diagnostic laboratory test that is separately payable.

**We recommend that CMS retain HCPCS code C9803 and its current APC assignment and status indicator beyond the COVID-19 PHE.**

## **PAYMENT FOR BLOOD NOT OTHERWISE CLASSIFIED (NOC) CODE**

Starting Jan. 1, 2020, CMS established a new HCPCS code, P9099 (Blood component or product not otherwise classified), which allows providers to report unclassified blood products before blood product-specific HCPCS codes are available. For CY 2020, HCPCS code P9099 has a status indicator (SI) of “E2” (Not payable by Medicare when submitted on an outpatient claim) because the code potentially could be reported for multiple products with different costs during the same period of time.

For CY 2021, CMS proposes to change the SI for HCPCS code P9099 from “E2” to “N” (payment is packaged into other services in the OPPS) and package the cost of the unclassified blood products into their affiliated primary medical procedure. In addition, CMS also seeks comment on the alternative proposal to make HCPCS code P9099 separately payable with a payment rate equivalent to the payment rate for the lowest cost blood product, HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), with a proposed CY 2021 payment rate of \$8.02 per unit. With the alternative option, the SI for HCPCS code P9099 would change from “E2” to “R” (blood and blood products, paid under OPPS).

**We agree with the Advisory Panel on Hospital Outpatient Payment recommendation that CMS change the SI to “R” for HCPCS code P9099, with a payment rate based on the weighted average of all blood/blood products APCs.** Providers should receive separate reimbursement for new blood/blood products, as they incur a cost for these products, and costs for new and existing products are not included in any current APCs since CMS does not package blood or blood products.

## **HOSPITALS WITHOUT WALLS**

During the PHE, CMS created a category of flexibilities called “Hospitals without Walls,” under which hospitals are able to establish and operate in any location as a PBD of the hospital, including a patient’s home, if they meet certain requirements. These flexibilities ensured that patients remained connected to essential services from the safety of their homes and hospitals retained inpatient capacity for those who need it most. Indeed, the Hospitals without Walls waivers had a profoundly positive effect on hospitals’ abilities to manage the pandemic; they enabled patient access to services delivered by hospital clinical staff – such as diabetes self-management training, medical nutrition therapy, and behavioral health counseling, and many others – and ensured hospital administrative staff could continue to support providers delivering virtual services and patients receiving those services. This is especially important given the numerous added steps hospitals must undertake to execute a virtual visit. These steps include:

equipping providers with necessary hardware; acquiring professional licenses for each physician on the virtual platform the hospital chooses; conducting separate communication with patients to test software, complete pre-registration, obtain and record patient consent, and conducting intake before a visit and follow-up after it, all of which would normally be done in person.

Our members report that patients have been extremely satisfied with their experiences receiving virtual care from all of the places they can currently access in-person care, including hospital outpatient departments. Patients have found that the convenience, quality and ease of receiving care in this manner helps accommodate their individual needs and lifestyles, creating a safer, more patient-centered care experience. **As such, we urge CMS to continue the Hospital without Walls flexibilities to the greatest extent possible. We recognize that this may require legislation and urge the agency to work with us and Congress to ensure hospitals and health systems can continue providing high-quality virtual care for their patients and communities.** We refer you to our [comments](#) the CY 2021 Physician Fee Schedule proposed rule for additional recommendations on virtual care.

## **PROPOSED CHANGES TO THE LIST OF ASC-COVERED SURGICAL PROCEDURES**

Proposed Additions to the List of ASC-covered Surgical Procedures. CMS conducted its annual review of procedures paid under the OPPS, but not included on the list of covered ASC procedures. As a result, for 2021 CMS proposes to add 11 procedures to the ASC-covered procedures list (CPL). Among these is CPT code 27130, Total Hip Arthroplasty (THA).

**We urge CMS not to add THA to the ASC-CPL, as it would be clinically inappropriate.** Specifically, doing so would pose serious risks and have negative quality of care implications for vulnerable Medicare patients. THA is a complicated, invasive surgical procedure, with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period. While these procedures may be successfully performed in an ASC for some non-Medicare individuals, we do not believe it is appropriate for the Medicare population. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which will make even a simple procedure more complicated.

Further, patients who undergo THA experience significant post-operative pain, which AHA believes is best managed in hospital-based settings. Managing post-operative pain for THAs performed in ASCs affects the ability to get appropriate and timely ancillary support, which is exacerbated by socioeconomic barriers that can often result in delays in care. We believe that there likely would be few, if any, Medicare beneficiaries who could safely be discharged home the same day after undergoing a THA, as would occur if this procedure were furnished in an ASC. This setting would not afford patients

enough time to recover properly or allow providers to address all post-surgical concerns — including any problems that arise with comorbidities. There is significant concern with ensuring that Medicare patients would be able to be discharged into a safe home environment, creating potential issues with patient safety and an increase in hospital admissions.

**Moreover, the AHA notes that CMS presumes that shifting services to “lower-cost” settings, like ASCs, would reduce beneficiary out-of-pocket costs. However, the opposite appears to be true for THA; beneficiaries will most likely face higher copayments in ASCs than in HOPDs.** This is because, in the HOPD, the beneficiary copayment amount is capped at the inpatient deductible amount, which is \$1,408 in 2020<sup>23</sup>. There is no copayment cap in ASCs. In the OPPI, CPT 27130 (THA) is part of C-APC 5115, Level 5 Musculoskeletal Procedures, proposed to be paid at \$12,559 in CY 2021. Therefore, the 20% copayment for C-APC 5115 (\$2,512) would exceed the Medicare Part A inpatient deductible and be capped at that amount. By contrast, in the ASC setting, there are no C-APCs or caps on the patient copayment amounts. Every separately payable ancillary service that is furnished in an ASC alongside THA would be subject to an additional 20% copayment. For CY 2021, CMS proposes a payment rate for CPT 27130 (THA) of \$8,924, which would result in a copayment of \$1,785. This is already \$377 more than the beneficiary copayment in the HOPD and does not even include all the other separately payable services likely furnished along with a THA in the ASC setting. Therefore, the out-of-pocket costs for Medicare beneficiaries could be significantly higher in an ASC than in an HOPD.

In addition to the inherent risks associated with THA for older patients and the higher co-payment that beneficiaries will face when these procedures are furnished in ASCs, part of our concern is that independent ASCs are often physician-owned and are not subject to the Stark self-referral regulations. Therefore, there may be other incentives in place for physicians in making a determination of the appropriate site-of-service.

Alternative Proposals for Adding New Procedures for the ASC-CPL. CMS proposes two alternatives that would each significantly modify the agency’s process for adding surgical procedures to the ASC-CPL. Under both alternatives, CMS would retain the general standards specified in regulations for adding ASC-covered surgical procedures, including that the procedures:

- Are separately paid under OPPI;
- Are not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC; and
- A beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure.

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<sup>23</sup> The 2021 inpatient deductible amount has not yet been announced but will likely increase in 2021.

However CMS would eliminate five of the general exclusion criteria currently in the regulations. Specifically, it would eliminate criteria that ASC-covered surgical procedures do not include surgical procedures that:

- Generally result in extensive blood loss;
- Require major or prolonged invasion of body cavities;
- Directly involve major blood vessels;
- Are generally emergent or life threatening in nature; and
- Commonly require systemic thrombolytic therapy.

Further, CMS would revise another general exclusion criterion which currently excludes procedures on the IPO list from being added to the ASC-CPL. That is, in light of the proposed elimination of the IPO list, CMS proposes to modify this criterion to exclude procedures that were on the IPO list as of Dec. 31, 2020 from being added to the ASC-CPL.

Under Alternative 1, in addition to making the changes to the regulatory exclusion criteria described above, CMS would solicit nominations from external stakeholders for procedures that could be added to the ASC-CPL. CMS would make final determinations regarding which nominated procedures would be added to the ASC-CPL through annual rulemaking. The nomination process would begin in 2022, which would result in surgical procedures potentially being added to the ASC-CPL beginning in 2023.

Alternative 2 would have a more immediate and potentially broader impact on the ASC-CPL. As with the first, in this second alternative CMS proposes to make all the same changes to the regulatory exclusion criteria as described above. While CMS would use a process similar to its current annual review process, the reduced number of regulatory exclusion criteria would result in procedures being added to the ASC-CPL more quickly. In fact, the agency identifies 270 possible surgery or surgery-like codes that it believes would meet the proposed revised criteria for 2021. CMS also seeks comments on whether it should revise the ASC Conditions for Coverage (CfCs) or quality metrics in response to an expanded range of services that may be covered under Medicare in the ASC setting.

**The AHA strongly opposes both proposals to modify the agency's process and criteria for adding surgical procedures to the ASC-CPL.** The current regulatory general inclusion and exclusion criteria serve two critical purposes. First, they are important patient safety guardrails intended to exclude from coverage those procedures that would pose a high-risk of complications that ASCs are not equipped to handle. Second, they allow appropriate surgical procedures to be added to the ASC-CPL. **It is not appropriate for CMS to eliminate such meaningful patient safety guardrails. For example, the agency should not eliminate a criterion that prevents a provider that does not have emergency capabilities from conducting surgeries that are**



**emergency or life-threatening in nature. Therefore, the AHA strongly recommends that CMS preserve these five general exclusion criteria.** As has been demonstrated in recent years, the existing ASC regulatory criteria have supported the ability of ASCs to safely furnish an expanding range of surgical procedures as innovations in surgical care occur. However, because ASCs are not subject to the same level of regulatory oversight as hospitals and are not equipped to manage emergencies that require lifesaving hospital inpatient capabilities, keeping these general exclusion criteria in place will prevent surgical procedures that pose significant threats to beneficiary safety and quality of care from being performed in in ASCs. **Furthermore, although the AHA strongly opposes CMS's proposal to eliminate the IPO list, as stated above, if the agency were to nevertheless finalize this policy, we also urge CMS to finalize its proposed revision that would prevent procedures that were on the IPO list as of Dec. 31, 2020 from being added to the ASC-CPL.** Procedures that would be removed from the IPO during the proposed three-year phase-out have not been evaluated for clinical appropriateness in a hospital outpatient department setting and are clearly inappropriate for coverage in the ASC setting.

**In addition, the AHA strongly opposes CMS's proposal, under Alternative 2, to add 270 surgery or surgery-like codes to the ASC-CPL that it believes would meet the proposed revised criteria for 2021.** CMS proposed these additions without taking into consideration the five regulatory exclusion criteria it has proposed for removal, and which we believe are essential to protect beneficiaries. The agency also does not provide any rationale that these procedures meet even the general regulatory standards for adding ASC-covered surgical procedures that CMS proposes to retain. **For example, CMS did not provide any evidence that these procedures are not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, or that a beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure. In fact, many of the procedures CMS proposes would *not* meet the agency's own criteria and we are extremely confused as to why it is proceeding down this path.** For instance, consider CPT code 21172, Reconstruction of the superior-lateral orbital rim and lower forehead; CPT code 37619, Ligation of inferior vena cava, and CPT code 63016, Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, more than 2 vertebral segments. The American Medical Association's Relative Value Update Committee assigns a total service time for each of these services of 11 hours or more. **As such, not only would these procedures pose a significant safety risk to the beneficiary if done in an ASC, but also, given their duration, they would likely require active medical monitoring and care at midnight following the procedure.** These are just a few of the many procedures included among the 270 CMS proposes for ASCs that would be safer to perform in a hospital-based setting.

**Furthermore, although the AHA strongly opposes the proposed changes to the ASC-CPL process and criteria, if the agency were to nevertheless finalize either proposed Alternative 1 or 2, we urge it to work with clinical experts and other stakeholders to make appropriate changes to the ASC CfC in response to the expanded range of higher risk services that would be covered in the ASC setting.** There are complications associated with any major surgery, such as anesthesia-related risks, allergic and other medication reactions, and those related to comorbid medical conditions. ASCs are not equipped to handle such life-threatening events, and we anticipate that if CMS finalizes its proposal, many patients would be sent emergently from ASCs to the nearby hospital ED when such complications arise. Therefore, we recommend that CMS start by restoring some of the beneficiary protections that the agency recently removed.

In last year's Medicare and Medicaid burden reduction final rule<sup>24</sup>, CMS weakened the CfC requirements that mandate that there is a plan in place in the event such emergencies arise. That is, it eliminated the requirement that ASCs have a written transfer agreement with a nearby hospital or ensure that its physicians have admitting privileges at a hospital. Instead, the agency now only requires ASCs to periodically provide the local hospital with written notice of its operation and patient population served. As a result, if a patient has a medical emergency that cannot be addressed within the capabilities of the ASC, it need only call an ambulance and send the crashing patient to the nearest hospital ED, without any further responsibility for the beneficiary's condition. **In light of the proposal to add so many complex, invasive surgical procedures to the ASC-CPL, CMS should restore the CfC requirements regarding written hospital transfer agreements or physician admitting privileges at a hospital.**

**Furthermore, with a broad expansion in the number and kinds of procedures that are proposed for addition to the ASC-CPL, including procedures that may have never been furnished in this setting, even greater oversight is necessary to protect Medicare beneficiaries. CMS should consider coordinating with clinical experts on enhancements to the anesthesia, emergency equipment and discharge planning standards.** The agency suggests several possible changes that AHA agrees may be worth pursuing, including:

- That risk evaluations should be more prescriptive and attest that an individual patient can safely undergo the procedure in an ASC;
- A requirement that an adequate number of nurses be on duty in the ASC;
- A requirement that staff certified to provide Advance Cardiac Life Support be present in the ASC in the event of life threatening emergencies; and
- Specific CfC requirements that ASCs would need to meet for particular patient conditions or more complex and invasive surgical procedures.

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<sup>24</sup> <https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>.

Finally, in addition to the inherent risks associated with more complex services being performed in the ASC setting, beneficiaries may also unexpectedly face higher out-of-pocket costs for surgeries performed in an ASC than they would if the services were furnished in a hospital outpatient department. This is especially a concern because physician-owners of ASCs are not subject to the Stark self-referral regulations and so may have a personal financial interest in performing surgery at an ASC instead of a hospital. **To ensure that beneficiaries are aware of this potential increased financial liability, the AHA recommends that the ASC CfC patient rights section be revised to include a condition requiring that ASCs inform patients in writing, prior to their procedure, of their copayment obligation and that, by virtue of services being performed in an ASC rather than a hospital outpatient department, they may be incurring higher out-of-pocket cost, and the difference in amount.**

## OVERALL HOSPITAL STAR RATINGS PROPOSALS

CMS proposes to implement significant modifications to the overall hospital star ratings methodology starting in CY 2021, and to codify a number of existing procedures and policies in regulation. Among other changes, CMS would simplify the calculation of measure group scores by eliminating the use of latent variable modeling (LVM). CMS also proposes to calculate hospitals' readmission measure group scores by placing hospitals into one of five peer groups based on their proportion of dual-eligible patients, an approach aligned with that of the Hospital Readmissions Reduction Program (HRRP). Lastly, before determining the final overall star rating, CMS would place each hospital into one of three peer groups based on the number of measure groups it reports. We comment on these and several other star ratings proposals below.

General Considerations. As longstanding supporters of transparency, America's hospitals and health systems believe that patients, families and communities should have valid, clear and meaningful quality information to help them make important health care decisions. That is why the AHA has long urged CMS to address the substantial flaws in the current star ratings methodology. As noted in our [response](#) to the agency's star ratings RFI in 2019, we believe the "must have" elements to any star ratings approach include:

- *Usefulness to consumers.* The ratings should provide information that is relevant to the wide range of reasons patients seek hospital care, and give consumers the ability to drill down on the particular aspects of care most relevant to them.
- *Accuracy.* The ratings should be based on rigorous quality measures, and employ appropriate, correctly-executed statistical approaches to combining performance across measures. Users and hospitals should expect that differences in star ratings across hospitals are substantiated by clinically and statistically meaningful differences in underlying performance.

- *Stability.* Any fluctuations in star ratings across reporting periods should be driven by significant changes in underlying measure performance rather than by any inherent instability in the ratings methodology.
- *A “line of sight” from star ratings to performance on underlying measures.* Because star ratings are publicly reported, hospitals should be able to see how any positive or negative changes in underlying measure performance are reflected in their star ratings in a transparent and predictable fashion.
- *Balanced assessment.* Star ratings performance should be based on performance across the breadth of available measures, and not hinge disproportionately on only one or two measures.
- *Accounts for potential biases.* The ratings must account adequately for differences in the clinical and social risk factors across the patients and communities that hospitals serve. Hospitals that serve sicker and poorer patients should be on a level playing field with all other hospitals.

**The AHA commends CMS for proposing changes that attempt to address all of these elements in a serious way. We urge CMS to adopt its proposals to discontinue the use of the LVM approach to measure group scores, and to stratify hospital readmissions measure group scores by the proportion of dual-eligible patients. However, while we agree with the intent behind CMS’s proposal to peer group hospitals, we encourage the agency to explore additional alternative peer grouping approaches before finalizing it.**

Lastly, our support for many of CMS’s proposed changes notwithstanding, we continue to question the basic concept of a single, overall rating of hospital performance. That is because the measures included in the ratings were never intended to create a single, representative score of hospital quality. Furthermore, the ratings often do not reflect the aspects of care most relevant to a particular patient’s needs. For example, a family may be interested in selecting the best hospital for cancer care, but there is only one such measure included in the current star ratings. In addition, there is vast variation in the type, scope and mix of services that hospitals provide. **For these reasons, we continue to encourage CMS to consider developing an alternative approach in which star ratings are done only by topic area such as patient safety, patient experience of care and cardiac care.** This approach may increase the relevancy of ratings information to consumers, and lessen the possibility of consumers receiving misleading information about quality.

**Reorganization of Measure Groups. The AHA supports CMS’s proposed reorganization of star ratings measure groups.** Specifically, CMS would consolidate the current effectiveness of care, timeliness of care and efficient use of medical imaging

groups into a single group called “Timely and Effective Care,” and give it a weight of 12%. We agree that because so many of the measures in the previously separate measure groups have been removed from CMS programs, it would be both conceptually and statistically inappropriate to retain separate measure groups.

**Measure Group Scores – Elimination of LVM in Favor of Simple Average.** **The AHA supports CMS’s proposal to discontinue the use of the LVM approach in calculating measure group scores and instead use a simple average of measures in the group.** The LVM combines actual measure performance with statistical assumptions about unobserved (or latent) dimension of quality that are based on available measure data. While CMS initially adopted LVM in an attempt to provide statistical rigor, our members have raised two major concerns about its use in star ratings. First, LVM is an inherently complex statistical modeling technique, impinging on hospitals’ “line of sight” between how their underlying measure performance translated into a star rating. This made it hard for hospital leaders to explain to staff, governance boards and the public why they may have received a particular rating, and what they could do to improve it. Given how public the ratings are, the lack of transparency introduced by LVM is unacceptable.

Second, the LVM introduced unwarranted volatility into star ratings, stemming from the LVM’s approach to calculating measure “loading factors.” Because each measure’s loading factor can change when CMS calculates it each year, the degree to which any one measure drives performance in a measure group also can change. As a result, the ratings were of virtually no use to internal quality improvement efforts, and hospitals had extremely limited ability to prioritize improvement efforts on any particular measures within star ratings. As noted in the previous section, we believe changes in star rating performance must be based on real changes in underlying measure performance, rather than the inherent design of the methodology.

We agree with CMS that taking an average of the measures in the group would result in a less statistically rigorous approach to star ratings. However, the benefits of transparency far outweighs that drawback. Hospitals would now know exactly what weight particular measures would have in star ratings, and follow a simple calculation of how measure scores would be summed into a group score. Using a simple average also makes it possible to use star ratings as one mechanism to track progress on internal improvement priorities. This approach would also make it more transparent to the public what weight is applied to each of the measures. For example, most would likely be unaware that because of the LVM, three measures – hip/knee complications, hospital-wide readmissions and the claims-based patient safety indicator measure – were previously driving nearly all of the determination of what star rating a hospital received. Other measures of greater importance to patient safety, such as health care associated infections, had very little weight.

**Measure Group Scores – Stratifying the Readmissions Measure Group.** **The AHA supports CMS’s proposal to stratify the calculation of readmission measure**

**group scores by hospitals' proportions of dual-eligible patients using an approach consistent with that of the HRRP.** This proposal responds directly to our recommendation to ensure a level playing field among hospitals in calculating star ratings. In addition, the alignment between the HRRP and star ratings approach to dual-eligible stratification is especially welcome since most hospitals already are familiar with the HRRP's approach, and would have to track only one approach to dual-eligible stratification. However, we note that the HRRP's stratification approach will be new for any CAHs receiving a readmissions group score because CAHs do not participate in the HRRP. For that reason, we encourage CMS to target technical support resources to CAHs to help educate them on the approach. This includes webinars, fact sheets and potentially a CAH-targeted "dry run" so that they know which peer group to expect when they receive preview reports.

A body of peer-reviewed literature shows that performance on readmission measures is driven not only by the quality of hospital care, but also by social risk factors beyond hospitals' control, such as income and insurance status. To date, hospitals caring for sicker patients and poorer patients tend to fare worse on star ratings. Specifically, teaching hospitals, hospitals that report on larger numbers of star ratings measures, and hospitals receiving the highest disproportionate share hospital (DSH) payments (a proxy for the extent to which hospitals serve the poor) all have ratings that are, on average, lower than other hospitals. For that reason, the AHA has long urged CMS to account for the impact of social risk factors in calculating star ratings. While a range of outcome measures may require adjustment, we have urged CMS to prioritize a social risk factor adjustment for the readmissions measure group.

**While we support CMS's proposal, the AHA continues to urge CMS to view stratification as an interim strategy while it assesses ways to improve its approach to accounting for social risk factors in readmission measures.** As we have noted with CMS's implementation of dual-eligible peer grouping in the HRRP, there are some inherent shortcomings with stratification, including somewhat subjective choices about where to set the cut points of a particular group. For example, those hospitals at the upper end of one group and those at the lower end of the next group would have similar proportions of dual-eligible patients, but would be placed into different groups for performance comparison purposes. Furthermore, direct risk adjustment would help improve the precision of performance comparisons by ensuring that measure scores reflect the issues most relevant to each measured outcome. For example, the stratification approach relies on the assumption that dual-eligible status is equally large determinant of performance for all of the readmission measures, when in fact, the impact of dual-eligible status may be slightly different for each measure.

In exploring alternative approaches to accounting for social risk factors, we also urge CMS to reject the findings of the recent report from the Assistant Secretary for Planning and Evaluation (ASPE) that CMS cites in the rule. ASPE's report contends, among other things, that adjusting for social risk factors is inappropriate, and recommends the removal of the HRRP's stratification approach. Indeed, we are perplexed by these

findings given that they run counter to the ample peer-reviewed literature showing the extent to which social risk factors drives performance. Indeed, ASPE itself issued a report in 2016 showing that social risk factors had an impact on nearly every CMS quality measurement program. Furthermore, we note that CMS does not have the statutory authority to remove dual-eligible stratification from the HRRP unless it adopts an alternative approach to accounting for social risk factors in calculating readmissions performance.

Star Rating Reporting Thresholds. **The AHA supports CMS's proposal to change the star rating reporting thresholds.** CMS proposes that hospitals would receive a star rating only if they report at least three measures in at least three measure groups, one of which must be mortality or safety. We agree with the agency that these two topics are of foundational importance to both patients and hospitals.

Assignment of Hospitals to Peer Groups. **The AHA agrees with the principle behind CMS's proposal to peer group hospitals by the number of reported measure groups. However, we encourage CMS to continue exploring additional alternative peer grouping approaches before finalizing this approach.** The current star ratings methodology compares all hospitals that meet the inclusion criteria directly to one another. Yet, as CMS notes, hospitals have significant variations in size, patient volume, case mix and services provided. As a result, many stakeholders have suggested the current methodology may result in potentially misleading comparisons among hospitals. In response, CMS proposes to place hospitals into one of three peer groups based on the number measure groups they report.

Peer grouping approaches attempt to create groupings of hospitals that are similar to one another on one or more specific characteristics, and compares performance within those groupings. We agree with the basic concept behind peer grouping – that is, it may be fairer to compare hospitals that are similar to one another than it is to compare hospitals with very different characteristics. However, the most challenging aspect of designing any peer grouping approach is selecting the variable(s) around which the groupings are organized. Generally speaking, peer grouping variables should be collected in a consistent manner, be consistently associated with star ratings performance, but also be characteristics over which hospitals have little influence. Hospitals have suggested CMS consider a variety of potential peer grouping variables, including bed size, case mix index, number of reported measures, teaching status, CAH designation and proportion of dual-eligible patients, to name just a few.

In this case, CMS proposes to use the number of reported measure groups because it has a clear, consistent definition, and the agency believes it is a reasonable proxy for a number of other characteristics, including patient mix and bed size. We certainly agree that the number of reported measure groups is easy to calculate. Yet, it less clear whether this characteristic is as strong a proxy for other underlying factors as CMS believes, and unfortunately, the analysis CMS includes in the rule does not allow us to assess this question directly.

Furthermore, we note there are significant differences in the sizes of the three peer groups, making us question the extent to which comparability is improved. CMS estimates that 10% of hospitals report three measure groups, 17% report four measure groups, and 73% report five measure groups. We believe the sheer size of the largest peer group means that the hospitals within it would continue to have significant variation in bed size and patient mix. For example, it would be possible for a smaller hospital to report all five measure groups, but report only the minimum number of measures (3) within each group. That hospital could be compared directly to a large hospital with enough volume and breadth of services to be scored on all measures included in star ratings.

Lastly, we note that the measures used in star ratings will continue to evolve in the coming years. CMS's Meaningful Measures initiative has removed a significant number of measures from hospital programs. While we strongly supported CMS's decision to streamline measures, it has implications for how many measures particular hospitals will be able to report. This may make the proposed approach to peer grouping inappropriate. Furthermore, the COVID-19 PHE prompted CMS to suspend quality reporting for the first two quarters of 2020, and may result in hospitals using the agency's extraordinary circumstance exceptions (ECE) policies to opt out of reporting for the rest of 2020. This also could affect a peer grouping approach based on the number of reported measure groups and potentially distort the sizes of the peer groups in unanticipated ways.

For these reasons, we encourage CMS to continue exploring a number of alternative approaches to peer grouping variables. For instance, the agency could examine whether it can create a composite of several characteristics – such as bed size, case mix, number of reported measures, teaching status, and the like – to use in organizing peer groups. Or, it could create peer groups based on the number of reported measures, instead of the number of measure groups. In exploring such changes, we urge CMS to make any analyses public, and to consult experts in the field using its existing Technical Expert Panel, the National Quality Forum, listening sessions and other mechanisms.

**Critical Access Hospitals. The AHA supports the continued inclusion in star ratings of those CAHs that choose to report quality data and opt into having their star ratings reported publicly.** While CAHs are not required to participate in the CMS hospital quality measurement programs, many opt to submit quality measure data, and appreciate the opportunity to see how their star ratings performance might compare to that of other CAHs and other hospitals.

**The AHA also supports the structure of CMS's proposed "opt out policy."** We also encourage CMS to provide ample technical assistance to CAHs – including webinars, ongoing communications and help desk assistance – to ensure they know how to avail themselves of the final opt-out policy.



Veterans Health Administration (VHA) Hospitals. **While we are open to the concept of including VHA hospitals in star ratings, AHA urges CMS not to finalize a policy to include them until it provides additional details on how it would operationalize such a policy.** Beginning in CY 2023, CMS would include VHA hospitals in star ratings. Citing the same authority under section 1704 of the Public Health Service Act as it does for CAHs, CMS notes its interagency agreement with the VHA would allow it to publish their hospitals' quality data.

Yet, it is not clear whether VHA hospitals are – or will – report on all of the same measures as the other hospitals included in star ratings. Furthermore, as CMS notes, even if VHA hospitals do report the measures, they are not included in Medicare quality reporting programs. The statistical impact of VHA hospitals on many measures – especially those based only on Medicare claims data – is simply unknown at this point. Unless and until the agency can provide additional detail, we do not think it would be appropriate to add VHA hospitals to star ratings.

Frequency and Timeframe of Star Rating Updates. **The AHA supports CMS's proposal to continue updating star ratings once per year.** We agree this approach should help make the ratings more stable, and allow hospitals additional time to know how their performance on the underlying measures might translate into a star rating.

Star Ratings Suppression for Subsection (d) hospitals. **In general, the AHA supports CMS's proposed star ratings suppression policy for subsection (d) hospitals.** Such hospitals must participate in CMS hospital quality programs. CMS would suppress the publication of star ratings only under circumstances that affect numerous hospitals as determined by CMS, or when CMS is at fault.

**However, we urge CMS to consider adding a criterion in which it suppresses ratings in the event a hospital or one of its agents (such as an authorized vendor) submits inaccurate data.** We agree with CMS that hospitals have mechanisms within existing reporting programs to correct underlying data before they are submitted. However, it is still possible that even after a hospital reviews the data their vendor intends to submit, there can be data transmission problems that hospitals may not pick up on until the star ratings preview period. We believe such instances would be extremely limited, but believe the agency should provide a mechanism to suppress the ratings when there is insufficient time for the data to be corrected before publication.

## **PROPOSED REVISION TO THE LABORATORY DATE OF SERVICE POLICY UNDER THE CLINICAL LABORATORY FEE SCHEDULE**

Many hospitals do not perform in-house more technologically advanced laboratory tests, such as molecular pathology and advanced diagnostic laboratory tests (ADLTs)<sup>25</sup>, which use specimens collected from hospital outpatients. Rather, upon receipt of a physician's orders, hospitals often send patient specimens to independent laboratories for testing. However, hospitals still often must bill Medicare for these laboratory tests that they do not perform due to CMS's laboratory date-of-service (DOS) policy and the "under arrangements" regulations. In these circumstances, the laboratory must seek payment for these tests from the hospital.

In the CY 2018 OPPS/ASC final regulation, in response to concerns that the DOS policy was administratively burdensome for hospitals and for the laboratories that furnish these tests and that it created delays and other barriers to patient access to critical diagnostic testing, CMS established an exception. This exception enables independent laboratories performing certain ADLTs and molecular pathology tests excluded from the OPPS laboratory test packaging policy to bill Medicare directly for those tests, instead of requiring them to seek payment from the hospital. The exception established that the DOS for molecular pathology tests and certain ADLTs is the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter;
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

When all conditions under the exception are met, the independent laboratory performing the test bills Medicare directly for the test under the CLFS.

Proposed Revision to Laboratory DOS Policy. In the proposed rule, CMS notes that the pattern of clinical use of cancer-related, protein-based MAAAs, similar to molecular pathology tests and ADLTs, make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient and are instead used to guide future treatment through surgical procedures or chemotherapeutic interventions.

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<sup>25</sup> ADLTs are tests that are performed by a single laboratory only and meet other criteria specified in statute.

**Therefore, for the same reasons that CMS proposes to no longer package cancer-related protein-based MAAAs under OPPS, CMS also proposes to apply the DOS exception to these MAAA tests.** This proposed revision to the laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs to bill Medicare directly for those tests instead of seeking payment from the hospital when the service is not packaged and the DOS policy described above is met.

**The AHA supports this proposed policy.** It would create consistency between the laboratory DOS rules and the proposed change for the OPPS laboratory test packaging policy for MAAAs. Further, this change would improve access to critical diagnostic testing services for Medicare beneficiaries while reducing hospital administrative burden.

## **PHYSICIAN-OWNED HOSPITALS (POH)**

For decades, the Stark Law has protected federal health care programs from the inherent conflict of interest created when physicians self-refer their patients to facilities and services in which they have a financial stake. In 2010, based on a decade of research on the adverse impacts of POHs, Congress strengthened that protection by imposing a prospective ban on self-referral to new physician-owned hospitals.

In this rule, CMS proposes to remove certain restrictions on the expansion of POHs that qualify as high Medicaid facilities. Specifically, CMS's proposals would (1) allow high Medicaid facilities to request an exception to the prohibition on expansion of POHs more frequently than once every two years; (2) remove the restriction that expansion of POHs may not result in the number of operating rooms, procedure rooms and beds for which the hospital is licensed exceeding 200% of the hospital's baseline number of operating rooms, procedure rooms and beds; and (3) remove the limitation that expansion may occur only in facilities on the POH's main campus.

**The AHA strongly opposes the proposals in this rule and any other attempts to loosen the current restrictions on POHs.** Recent data reinforces the need for a ban on new and expanded POHs. Specifically, an [analysis](#) conducted by the health care economics consulting firm Dobson | DaVanzo provides a clear picture that the characteristics of these hospitals virtually mirror the those that, in the early-to-mid 2000s, drove Congress to prospectively ban self-referrals to new facilities. For example, Dobson | DaVanzo found that POHs:

- Cherry-pick patients by avoiding Medicaid and uninsured patients;
- Treat fewer medically complex patients;
- Have margins nearly three times those of non-physician owned hospitals;
- Provide few emergency services – an important community benefit; and

- Are penalized for unnecessary readmissions at 10 times the rate of non-physician owned hospitals.

Another, more recent analysis performed by DeBrunner & Associates conducted in August underscores the fact that non-POH hospitals treat the sickest, most vulnerable patients. Specifically, we found that on average, patients discharged from non-POHs are 36% more likely to have one or more chronic conditions. At the same time, non-POH hospitals provide 25% more uncompensated care as a share of total expenses. Both of these trends contribute to the fact that POH hospitals have, on average, an operating margin that is *57 times higher* than non-POH hospitals.

In fact, the Congressional Budget Office, MedPAC and independent researchers have all concluded that physician self-referral to facilities in which they have an ownership stake leads to greater per-capita utilization of services and higher costs for the Medicare program. Further, POHs tend to cherry-pick the most profitable patients, jeopardizing communities' access to full-service care. This trend creates a destabilizing environment that leaves sicker and less affluent patients to community hospitals, threatening the health care safety net.

The proposals in this rule run counter to the sum total of the research in that they would make it easier for certain POHs to expand, putting high-quality, reliable care at risk. However, we are concerned that CMS understates this potential for POHs to expand. The agency states in the rule that only one POH per year would request an expansion under these proposals. In contrast, our analysis demonstrates that approximately 25 facilities could qualify over the next three years. We urge CMS to, at the very least, release the data upon which it based its conclusion.

In addition, some of the POHs that qualify as "high Medicaid facilities," and would thus be able to expand under this proposal, have extremely low Medicaid discharge percentages. They clearly do not embody the intent of the exception. Specifically, while they may have the highest Medicaid discharge percentages in their counties, those percentages are significantly lower than that of hospitals in surrounding counties. For example, one POH has a Medicaid discharge of 1.9%. That is higher than the only other hospital in the county, a rehabilitation hospital, but it is much lower than hospitals in surrounding counties, which have Medicaid discharge percentages as high as 96.3%. There are several other examples of this discrepancy, including:

- A POH with a 16% Medicaid discharge percentage neighbors a county with a hospital that has a Medicaid discharge percentage of 28.33%.
- A POH with a 19.1% Medicaid discharge percentage neighbors two counties with hospitals that have Medicaid discharge percentages as high as 66.1%.
- A POH with an 18.8% Medicaid discharge percentage neighbors a county with a hospital that has a Medicaid discharge percentage of 44.6%.
- A POH with an 18.8% Medicaid discharge percentage neighbors a county with a hospital that has a Medicaid discharge percentage of 53%.

CMS's proposals also create perverse incentives to game the limited exception to the prohibition on expansion of POHs, threatening to bust it open. Specifically, POHs could work to temporarily meet the high Medicaid facility threshold, allowing them to undertake a significant expansion. Because there are no requirements in the proposal to continue meeting the high Medicaid facility criteria following any such expansion, these POHs could then return to rejecting Medicaid and other patients. There also appears to be no restrictions on how frequently high Medicaid facilities can expand. These proposals pose grave risk to the stability and integrity of patient care and should not be finalized.

## **PROPOSED PRIOR AUTHORIZATION REQUIREMENTS FOR ADDITIONAL OUTPATIENT SERVICES**

Continuing to cite its authority under section 1833(t)(2)(F)<sup>26</sup> of the Social Security Act and the regulations at 42 CFR § 419.83,<sup>27</sup> CMS proposes expand the prior authorization program it established in 2020 to two new service categories: cervical fusion with disc removal and implanted spinal neurostimulators. The prior authorization process for these two additional service categories would be effective for dates of services on or after July 1, 2021. The agency claims that these services have had an “unnecessary increase in the volume of services” and that a prior authorization policy would help to ensure these services are billed only when medically necessary.

**The AHA continues to oppose the OPPS prior authorization program and urges the agency to withdraw it. As stated in our CY 2020 comment letter, the prior authorization program is contrary to law because CMS must implement any methods developed under paragraph (t)(2)(F) through other provisions of the OPPS statute. In addition, the prior authorization program is arbitrary and capricious because the agency has not established that the increase in volume for these services is “unnecessary.”** Please refer to our Sept. 27, 2019 [comment letter](#) for additional information about these concerns.

CMS has not demonstrated that the increase on the volume of these services are “unnecessary.” In the proposed rule, CMS describes claims data for a 12-year period, from 2007 through 2018, showing increases in the volume for implanted spinal neurostimulators and claims data for a seven-year period from 2012 through 2018 showing an increase in the volume of service utilization for cervical fusion with disc removal. CMS asserts that the increases in volume for these services are unnecessary because: (1) the data show that the volume of utilization of these services exceeds what would be expected in light of the average rate of increase in the number of Medicare beneficiaries; (2) the agency is unaware of other factors that might contribute to

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<sup>26</sup> “(2) SYSTEM REQUIREMENTS.— Under the payment system—... (F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services.”

<sup>27</sup> 42 CFR § 419.83 - List of hospital outpatient department services requiring prior authorization.

clinically valid increases in volume, such as “legitimate clinical or coding reasons for the changes.”

**While CMS presents data on increases in the volume of these services, the agency has not demonstrated that these volume increases are “unnecessary.” Further, CMS fails to meaningfully seek out or analyze any alternative explanation for the increase in volumes it reports, instead it merely notes that it “did not find any explanations that would cause us to believe the increases were necessary.” These failings make the proposed prior authorization requirement arbitrary and capricious.**

It is “well established” that an agency has a duty to consider reasonable alternatives to its chosen conclusions and courses of action.<sup>28</sup> An agency may not adopt an “ostrich-like approach” to decision-making,<sup>29</sup> where “[n]ot having discussed the [alternative] possibilit[ies], the agency submit[s] no reasons at all” for why it adopts its explanation over other reasonable alternatives.<sup>30</sup>

In this case, the universe of reasonable alternative explanations includes, among other things, the possibility that volume is increasing because clinically appropriate and medically necessary demand is increasing, or because CMS’s own policies are incentivizing increased outpatient utilization of these services or otherwise encouraging the shifting of these services from inpatient to outpatient settings.

**As discussed below, there are medically necessary indications for both of the categories of procedures that would be subject to prior authorization, and shifts in national policy and CMS’s Medicare policies that could explain the increases in volume. It is disappointing that the agency chose not to undertake these types of relatively straightforward analyses, and instead chose to set forth unfounded proposals.**

*Implanted Spinal Neurostimulators.* A spinal cord stimulator (SCC) is an implanted device that sends low levels of electricity directly into the spinal cord to relieve pain. SCSs can be used to treat a variety of diseases that result in chronic pain. The most common indications include failed back surgery syndrome (FBSS) with radicular pain, complex regional pain syndrome (CRPS), peripheral neuropathy, phantom limb pain, angina, and ischemic limb pain.<sup>31</sup> Other FDA approved indications include multiple sclerosis, postherpetic neuralgia, post-thoracotomy pain, intercostal neuralgia and spinal cord injuries.<sup>32</sup>

CMS reports that claims data for the 12-year period from 2007 through 2018 show increases in volume for implanted spinal neurostimulator codes, including: CPT code

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<sup>28</sup> *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1511 (D.C. Cir. 1984).

<sup>29</sup> *Portland Cement Ass’n v. EPA*, 665 F.3d 177, 185 (D.C. Cir. 2011).

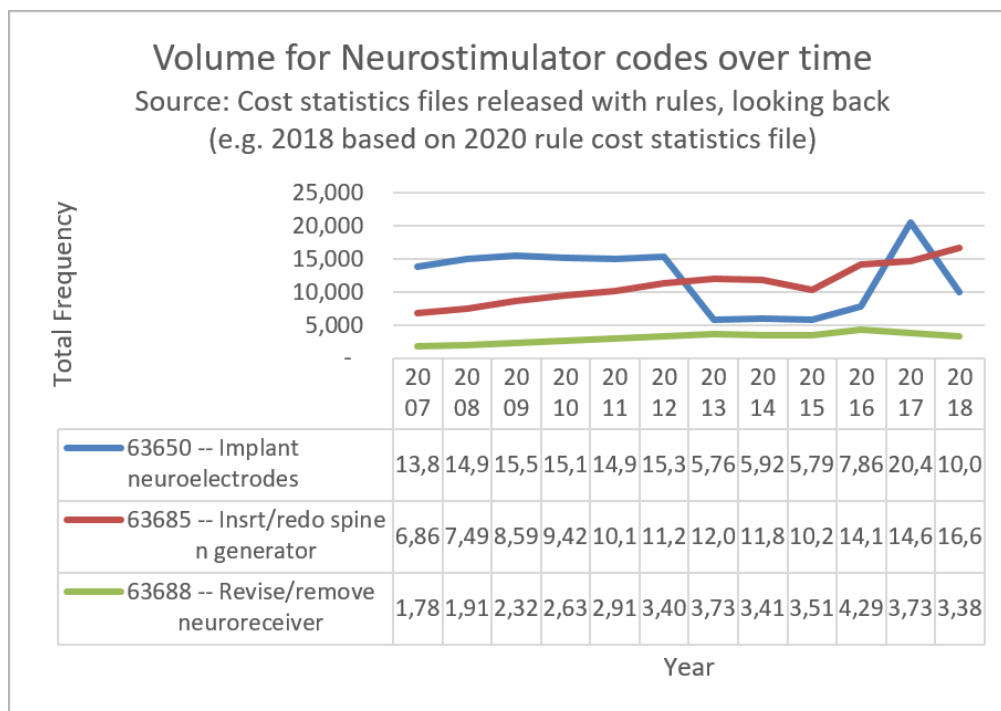
<sup>30</sup> *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

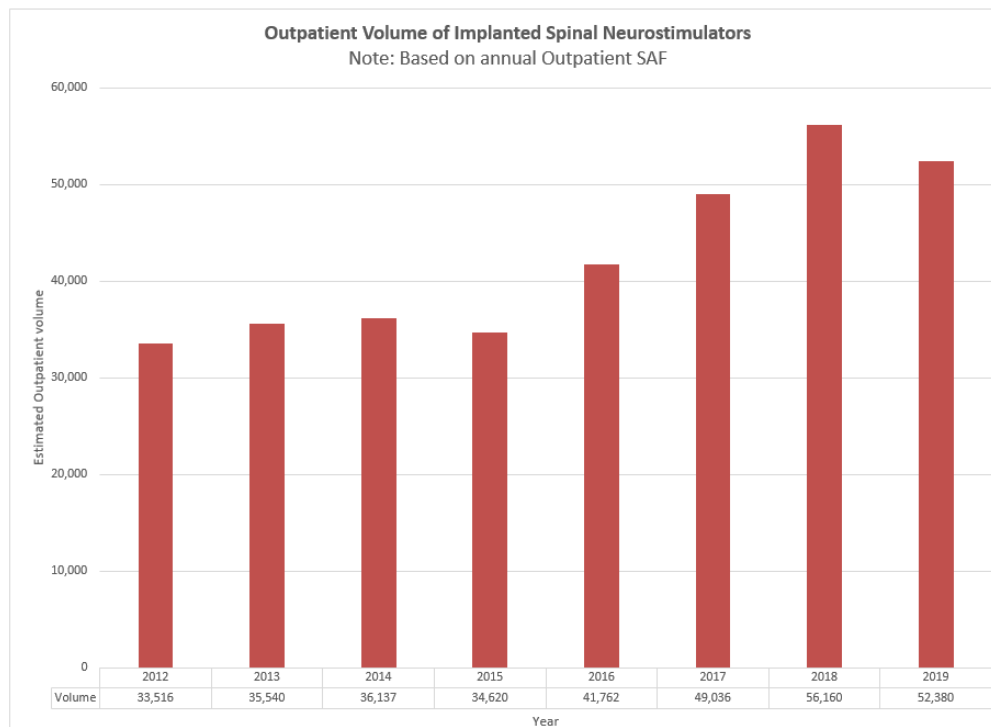
<sup>31</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3389317/>.

<sup>32</sup> <https://emedicine.medscape.com/article/1980819-overview#a3>.

63685 Insertion or replacement of spinal neurostimulator pulse generator or receiver; CPT code 63688 Revision or removal of implanted spinal neurostimulator pulse generator or receiver and CPT code 63650 Implantation of spinal neurostimulator electrodes, accessed through the skin. While the agency notes average increases in volume over this entire time period, it also stresses the significantly higher average annual increase in volume of 17% for CPT code 63685 for 2016 through 2018.

In the charts below, the AHA displays the volume trend for each CPT code over time as well as a chart showing the combined volume of all three implanted neurostimulator codes over time. These charts show relatively flat volumes through 2015, with significant increases in volume for 2016 through 2018.





**This increase in the utilization of these implanted spinal neurostimulators can be explained by the national focus on the opioid crisis and the subsequent efforts by the Administration and its multiple federal agencies to address the crisis. For instance:**

- In January 2017, CMS issued its Opioid Misuse Strategy, with the mission to impact the national opioid misuse epidemic by, among other things, increasing the use of evidence-based practices for acute and chronic pain management, including encourage the use of non-pharmacologic therapies, non-opioid pharmaceuticals, and multi-modal analgesia as first options for pain management.
- In October 2017, the Secretary of HHS declared the opioid crisis to be a national PHE under federal law.
- In November 2017, the President’s Commission on Combating Drug Addiction and the Opioid Crisis (Commission) issued a report that, among many other recommendations, requested that “CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain.”



In CMS's CY 2019 OPPS/ASC rulemaking, in response to the Commission's request, CMS finalized a new policy to un-package and pay separately for non-opioid pain management drugs that function as surgical supplies (initially just Exparel) when they are furnished in the ASC setting for 2019. While the agency declined to pay separately for these drugs in hospital outpatient departments, it noted that it would continue to analyze the issue of access to non-opioid alternatives.

CMS also indicated in the 2019 proposed rule that it was interested in evidence relating to products that have shown clinical improvement over other alternatives, such as devices that have been shown to provide a substantial clinical benefit over the standard of care for pain management. The agency noted as an example "spinal cord stimulators used to treat chronic pain," which CMS hinted could be proposed for separate payment (rather than packaged payment) if sufficient evidence were presented. In response, several manufacturers of SCCs commented that separate payment was warranted for such devices because they provide an alternative treatment option to opioids for patients with chronic, leg or back pain. Some manufacturers provided studies asserting that patients treated with their devices had decreased opioid use. In response, CMS noted that it would take these comments into consideration for future rulemaking and encouraged providers to use effective alternatives to opioid prescriptions when medically necessary.

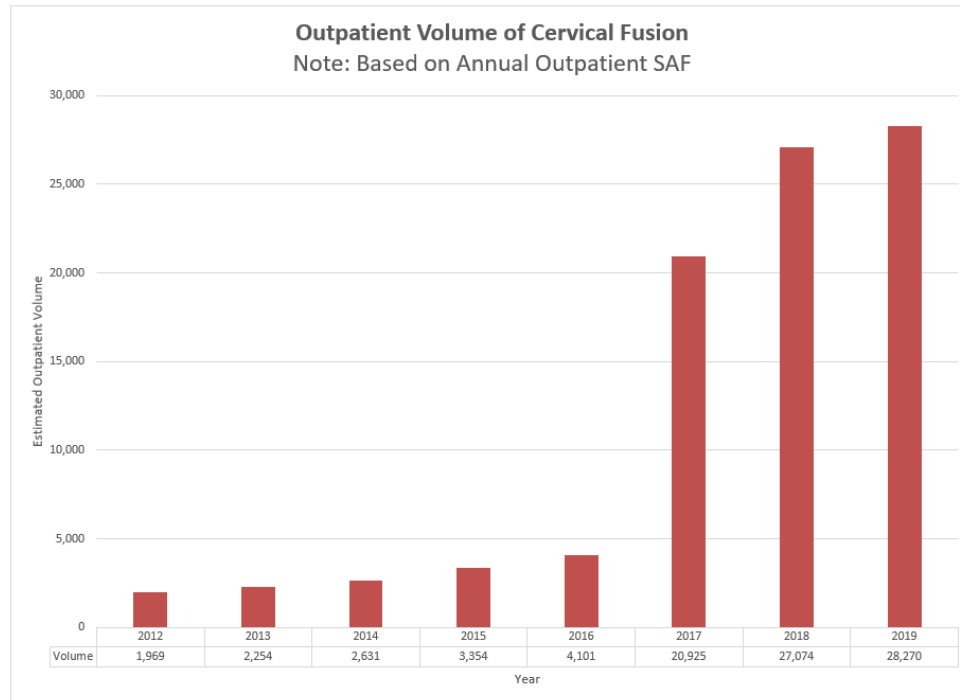
**Thus, intense national focus on reducing the use of opioids in medical and surgical care caused a nationwide focus on substituting the use of non-opioid pain management treatments and technologies to address pain. This is a reasonable explanation for the increased utilization of implanted neurostimulators, which are indicated for the treatment of chronic pain. Therefore, we urge CMS not to finalize its proposal to add the three implanted neurostimulator codes to its prior authorization list.**

*Cervical Fusion with Disc Removal.* This is a surgery to remove a herniated or degenerative disc in the neck. The indications for these procedures include cervical spine trauma and resulting instability, radiculopathy, myelopathy, osteomyelitis, spondylosis, vertebral body tumors, opacified posterior longitudinal ligament and postlaminectomy kyphosis.

In the proposed rule, CMS reports that claims data for a seven-year period, from 2012 through 2018 for cervical fusion with disc removal (codes CPT codes 22551 and 22552 (an add-on code)) show a "substantially greater increase than the 2.8% average annual increase for all OPD services over the same period." The agency focuses especially on a "dramatic" increase in volume between 2016 and 2018. In the chart below, the AHA displays the volume trend for the Cervical Fusion CPT codes over time.

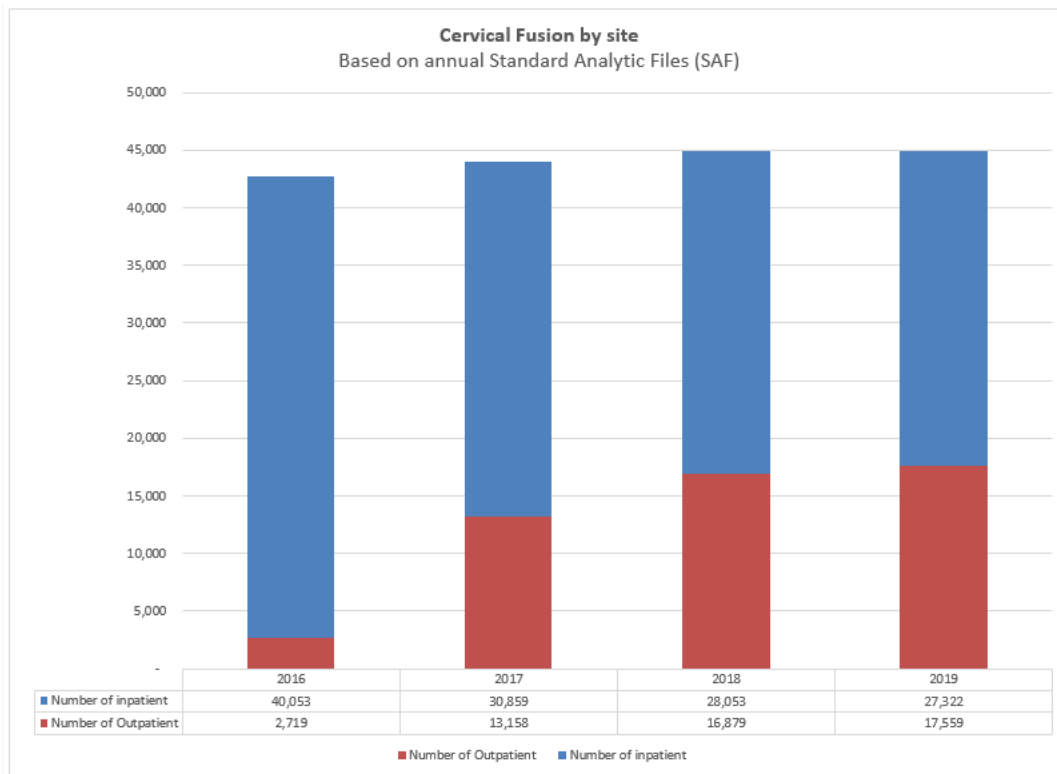
The agency suggests that this volume increase is due to the change in the APC assignment for CPT 22551 and 22552, in which these two codes were moved to a

higher level APC 0425, which increased the reimbursement rate, thereby creating a financial motivation for an unnecessary increase in utilization of these codes.



**The AHA disagrees. Instead, the outpatient increases in the volume of these services is clearly due to the shifting of these services from inpatient to outpatient settings.** In the proposed rule, CMS notes that the use of CPT 22551 “almost tripled in 2012 and significantly increased each year thereafter.” Indeed, 2012 is the exact year that CPT 22551 was removed from the IPO list. In CY 2016, CPT 22552 also was removed from the IPO list and is part of a complexity adjustment for the comprehensive APCs.

**In the chart below, the AHA demonstrates that there has not, in fact, been a significant overall increase in volume of these services in hospitals. Rather, with the removal of these procedures from the IPO list, the volume of procedures previously furnished in the inpatient setting shifted to the outpatient setting. This is not unnecessary. It is, in fact, the expected result when CMS removes services from the IPO list. Therefore, we urge CMS not to finalize its proposal to add the two cervical fusion with disc removal codes to it prior authorization list.**



**Given these shortcomings in CMS’s analysis, we strongly encourage the agency to explicitly incorporate into its prior authorization methodology a review of whether an outpatient service showing a higher than average increase in volume has recently been removed from the IPO list. This recommendation is especially important in light of CMS’s proposal to eliminate the IPO list over three years.**



Charles N. Kahn III  
President and CEO

October 5, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: CMS-1736-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals; Proposed Rule, Federal Register (Vol. 85, No.156), August 12, 2020**

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care across settings in both urban and rural areas. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the above Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register (85 Fed. Reg. 48772) on August 12, 2020.

## EXECUTIVE SUMMARY

### **Physician-Owned Hospital Expansion**

The FAH strongly opposes CMS’s proposal to effectively remove all limits on expansion by physician-owned “high” Medicaid facilities, including the frequency with which such a facility can request a capacity expansion; the caps on the number of operating rooms, procedure rooms, and beds that can be approved; and the requirement that expansion must only occur on the main campus. For multiple reasons, the proposal is much broader than purported in the Proposed Rule and its impact will far surpass only Medicaid patients, while opening the door for significant gaming by physician-owned hospitals (POHs) and thus undermining Congressional intent to strictly limit POH expansion.

There is no requirement that a high Medicaid facility in fact serve a high number of Medicaid patients. Instead, a “high” Medicaid facility is one that simply has a higher percentage of Medicaid admissions than the other hospitals in the same county. Our analysis reveals 24 facilities that either currently – or soon could – qualify. It also identifies one POH that qualifies as a “high” Medicaid facility with a FY 2018 Medicaid discharge percentage of only 1.9 percent in a county with only two facilities. Yet, hospitals in the neighboring counties have FY 2018 Medicaid discharge percentages of approximately 13 percent, 15 percent, and 22 percent. This points to the distinct possibility that this so-called “high” Medicaid POH, which also has far lower rates of uncompensated care costs and emergency room services, cherry picks patients, shifting the burden to neighboring county hospitals – exactly the behavior Congress intended to curtail when it enacted limits on POH expansion. And under the Proposed Rule, there are no limits to how often, how much, what services, and where, within a 35 mile limit, this “high” Medicaid POH could expand – or even that the POH must remain a “high” Medicaid facility under the relaxed standard that applies. The Proposed Rule also seeks feedback on removing any opportunity for the neighboring hospitals to comment on the POH’s request to expand, which we strongly oppose as this may be the only opportunity for CMS to obtain accurate data. In short, the proposal contravenes congressional intent and serves no public policy purpose.

### **OPPS Payment Methodology for 340B Purchased Drugs**

As in previous years, the FAH supports CMS’s 340B payment policy and maintains that CMS must continue to implement any such payment reduction prospectively in a budget neutral manner within the OPPS. Further, the FAH reiterates its position that if further judicial review of that policy results in a retrospective reversal of the policy, the Medicare Act does not permit CMS to make any prospective offsets to achieve actual or retrospective budget neutrality. Thus, the FAH would strongly oppose any effort to offset any remedy for 340B hospitals or to otherwise achieve budget neutrality by implicitly or explicitly recouping payments made for non-drug OPPS items and services in 2018 and 2019.

### **Proposed Elimination of Inpatient Only List**

The FAH strongly opposes CMS’s arbitrary proposal to eliminate the Inpatient Only (IPO) list, which designates those procedures that are not payable under the OPPS because they can only be appropriately provided on an inpatient basis. The assignment of procedures to the

IPO list takes into account key clinical considerations that preclude the procedure from being provided to Medicare beneficiaries on an outpatient basis: (1) the invasive nature of the procedure, (2) the need for postoperative care, and (3) the underlying physical condition of the patient who would require the surgery. The IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing any of the 1,740 procedures on the IPO list receive inpatient care and monitoring, and its proposed elimination without any supporting clinical analysis arbitrarily removes an important patient safety mechanism. In addition, eliminating the list imposes administrative burdens on physicians and hospitals, increases beneficiaries' financial burden, and erodes the value of Part A coverage.

### **ASC Covered Procedures List Criteria**

The FAH strongly supports CMS's proposal to continue to apply current policies and criteria for updating the ASC Covered Procedures List (ASC-CPL) and opposes both alternative options for modifying the process and criteria for additions to the ASC-CPL. The current standards and exclusion criteria for the ASC-CPL appropriately prioritize patient safety while still allowing the ASC-CPL to evolve with advancements in surgical care, and they should therefore remain in place. Although ASCs can safely perform a growing array of surgical procedures without having the capacity to provide inpatient care in the case of complications and without having satisfied other hospital conditions of participation (or being licensed and accredited as hospitals), ASCs should not be treated as the equivalent of hospital outpatient departments. ASCs are not regulated as hospitals, and since November 29, 2019, ASCs have not been required to have written hospital transfer agreements or hospital physician admitting privileges. Thus, procedures that pose significant patient safety risks (e.g., procedures that generally result in extensive blood loss, that require major or prolonged invasion of body cavities, directly involve major blood vessels, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy) should continue to be excluded from Medicare coverage in ASCs to ensure that Medicare beneficiaries receive these services in a setting that allows for rapid intervention and elevation of the level of care in the case of life-threatening complications.

The FAH also opposes adding THA to the ASC list in light of clinical concerns, expanded beneficiary coinsurance obligations for ASC procedures compared to hospital outpatient procedures, and the risks of providing payment for THA in physician-owned ASCs that are not subject to physician self-referral restrictions.

### **Hospital Quality Star Rating Methodology**

The FAH applauds CMS's recognition for the opportunity of a much needed refresh and appreciates the proposals aiming to ensure the methodology is transparent, understandable, with clear cut-points and targets, and accurately reflecting the quality of care provided in the facilities. Until this is achieved and the changes are implemented, however, the FAH urges CMS to suspend the Star Ratings from the Hospital Compare website.

## I. Proposed Wage Index Changes (Part II.C.)

***The FAH commends CMS’s continued commitment to supporting rural hospitals by mitigating the negative feedback loop created by the wage index through an increase to the wage index values of low wage index hospitals.*** Rural hospitals are imperative in ensuring access to care for the more than 60 million Americans living in rural areas across the United States, including close to one quarter of all Medicare beneficiaries.<sup>1</sup> Because Medicare beneficiaries disproportionately rely upon rural hospitals for care, Medicare reimbursement tends to impact rural hospitals’ revenue more than non-rural hospitals. As CMS noted in the FY 2020 IPPS rulemaking, the wage index has created a “downward spiral” whereby low wage index hospitals receive lower reimbursement, thereby weakening their capacity to invest in recruitment or employee retention, and further depressing reimbursement. As such, the FAH commends CMS’s proposal to continue its policy of increasing the wage index values for hospitals in the lowest quartile of the wage index values across all hospitals. ***The FAH, however, prefers that CMS reverse its budget neutrality adjustment associated with the low wage index hospital policy and instead apply the policy in a non-budget neutral fashion for CY 2021.*** Non-budget neutral implementation of this policy would avoid unnecessarily reducing OPPS reimbursement, particularly in the midst of the ongoing COVID-19 pandemic.

The Proposed Rule also proposes to adopt the updated OMB delineations and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage indices. Typically, OMB bulletins issued between decennial censuses have only minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18-03 and the September 14, 2018 OMB Bulletin No. 18-04 included more modifications to the labor market areas than are typical between decennial censuses, including a total of 34 counties and 10 hospitals changing from urban to rural, a total of 47 counties including 17 hospitals or critical access hospitals (CAHs) changing from rural to urban, and 19 urban counties that would shift from one Core-Based Statistical Area (CBSA) to a newly proposed or modified CBSA. The FAH supports CMS’s proposal to use the new OMB Bulletin No. 18-04 delineations, consistent with the IPPS FY 2021 wage index changes.

The FAH also supports CMS’s proposal to mitigate reductions in the hospital wage index due to the adoption of the updated OMB delineations and other factors by applying a 5 percent cap on any decrease in a hospital’s CY 2021 wage index, though we also strongly recommend that CMS not apply budget neutrality to offset the costs of this sound transition policy.

## II. OPPS Payment Methodology for 340B Purchased Drugs (Part V.B.)

In the Proposed Rule, CMS proposes to adjust the rate on a budget neutral basis for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired by a hospital outpatient department under the 340B program to ASP minus 34.7 percent, plus an add-on of 6 percent of the product’s ASP (*i.e.*, a net payment rate of ASP minus

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<sup>1</sup> MedPAC June 2018 Data Book, Section 2: Medicare Beneficiary Demographics (July 20, 2018).

28.7 percent). In CYs 2018 through 2020, CMS has applied a payment methodology of ASP minus 22.5 percent for these drugs and biologicals, effectuated in a budget neutral manner.

Regardless of the final rate CMS applies, as in previous years the FAH supports CMS's 340B payment policy and maintains that CMS must continue to implement any such payment reduction prospectively in a budget neutral manner within the OPPI, consistent with the requirements of 42 U.S.C. § 1395l(t)(9)(B). Thus, the FAH supports CMS's proposal to adopt an increase to the conversion factor to account for any change in 340B drug payment policy. Doing so would provide a net benefit to as many as 82 percent of all hospitals paid under the OPPI, including 89 percent of rural hospitals, 74 percent of government hospitals, and even 42 percent of 340B hospitals.

The Proposed Rule also includes a review of ongoing litigation concerning CMS's 340B payment policy in CYs 2018 and 2019, suggesting that if further judicial review of that policy results in a retrospective reversal of the policy, CMS would also reverse the associated budget neutrality adjustment for those years.<sup>2</sup> The FAH reiterates its respectful disagreement with CMS's assertion that CMS must or may craft a budget neutral remedy for its CY 2018 and 2019 340B-acquired drug payment policy. To the contrary, the Medicare Act does not permit CMS to make any prospective offsets to achieve actual or retrospective budget neutrality. ***To the extent that CMS is ultimately required to provide a remedy for 340B hospitals through a prospective payment increase designed to compensate such hospitals for any past underpayments, that payment increase cannot be adopted in a budget neutral fashion because any offsetting payment reduction would unlawfully recoup past payments that were properly made by CMS for non-drug OPPI items and services.*** Thus, the FAH would strongly oppose any effort to offset any remedy for 340B hospitals or to otherwise achieve budget neutrality by implicitly or explicitly recouping payments made for non-drug OPPI items and services in 2018 and 2019.

### III. Site Neutral Payment for Off-Campus Clinic Visits (Part VII)

***The FAH opposes continuation of the payment reduction for hospital outpatient clinic visits (HCPCS code G0463) furnished in an excepted, off-campus provider-based department (PBD).*** CMS has characterized this policy as a “method to control unnecessary increases in the volume of covered outpatient department services” under 42 U.S.C. § 1395l(t)(2)(F), but after two years of this policy, provides no data or analysis as to whether the payment reduction is in fact operating as such a method rather than as a blunt payment cut. The Proposed Rule does not assess the extent to which the volume of covered outpatient clinic visits has declined under this policy. Nor does it assess the extent to which the payment cut adversely impacts *necessary* covered outpatient clinic visits. And it does not endeavor to distinguish between the impact of section 603 of the Bipartisan Budget Act of 2015 (Section 603) and CMS's payment reduction for clinic visits in excepted, off-campus PBDs on the volume of unnecessary (and necessary) covered outpatient department services. These omissions are troubling as commenters to the CY 2019 Proposed Rule emphasized the significant limitations of the data that CMS relied on when originally proposing and adopting the payment reduction for hospital outpatient clinic visits in excepted, off-campus PBDs.

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<sup>2</sup> 85 Fed. Reg. at 48,884.



The proposed continuation of the payment reductions in CY 2021 is particularly troubling in light of the ongoing public health emergency due to COVID-19. Hospitals (including their off-campus PBDs) have played a vital role in the national response to COVID-19 and have suffered significant revenue impacts with the delay and cancellation of outpatient items and services. CMS, however, wholly fails to address these changed circumstances or their anticipated impact on outpatient clinic visits in CY 2021. Rather, the Proposed Rule provides no rationale for the apparent assumption that an unnecessary increase in the volume of covered outpatient clinic visits would occur in the midst of the COVID-19 pandemic absent continuation of CMS's site-neutral payment reduction. Nor does it provide a rationale for the assumption that the continued payment reduction would operate as an appropriate volume-control measure in these vastly changed circumstances. ***In short, despite the passage of time and significantly changed circumstances of a nationwide public health emergency, CMS proposes to blindly and improperly continue its policy without examining whether the payment reduction would actually operate as a "method to control unnecessary increases in the volume of covered outpatient department services" under 42 U.S.C. § 1395l(t)(2)(F) in CY 2021.***

In addition, as explained in the FAH's comments to the CY 20019 OPPS/ASC Proposed Rule, CMS's site neutral policy for excepted, off-campus PBDs continues to be flawed because it makes no allowance for the physician's professional judgment concerning the most appropriate site of service for the patient, ignores the significant costs borne by hospital outpatient departments, jeopardizes patient access to needed services, and is at odds with Congress' express determination in Section 603 that excepted PBDs are entitled to full OPPS reimbursement. Moreover, the FAH maintains that CMS's continued application of the payment reduction for services described by HCPCS code G0643 and billed with the "PO" modifier in a non-budget neutral fashion is improper and unlawful. Under 42 U.S.C. § 1395l(t)(9)(B), adjustments under subsection (t)(2) are required to be adopted in a budget neutral manner. Budget neutrality is not only required, but it is also appropriate in order to mitigate the risk that the payment cuts will adversely impact beneficiary access, particularly in the midst of the COVID-19 public health emergency.

#### IV. Payment for Partial Hospitalization Services (Part VIII)

The FAH supports the CMS decision in the Proposed Rule to (1) use the geometric mean per diem cost methodology for Partial Hospital Program (PHP) rates in accordance with its existing methodology for both hospital-based PHP and CMHC rates and (2) establish a separate cost floor for each category; \$121.92 CMHC's and \$222.76 Hospital-Based.

CMS stated that access to outpatient mental health services in the partial hospitalization setting is "better supported when the geometric mean per diem cost does not fluctuate greatly". The FAH concurs with this assessment and we believe the proposed policy will help ensure beneficiary access to this critical Medicare covered benefit will remain intact. Less volatility and adequate Medicare PHP rates year to year will ensure PHP programs retain their fiscal viability in the long term.

V. The IPO List Should be Retained as a Critical Patient Safety Tool and to Ensure that Procedures Are Appropriately Paid and Provided Under Medicare Part A (Part IX) (Proposed 42 C.F.R. 419.22(n))

The FAH strongly opposes CMS's proposal to eliminate the IPO list, which designates those procedures that are not payable under the OPPIs because they can only be appropriately provided on an inpatient basis. The assignment of procedures to the IPO list takes into account key clinical considerations that preclude the procedure from being provided to Medicare beneficiaries on an outpatient basis: (1) the invasive nature of the procedure, (2) the need for postoperative care, and (3) the underlying physical condition of the patient who would require the surgery.<sup>3</sup> The IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing any of the 1,740 procedures on the IPO list receive inpatient care and monitoring, and its proposed elimination without any supporting clinical analysis arbitrarily removes an important patient safety mechanism.

Instead, the FAH supports retaining the IPO list—which consists of procedures that are currently performed appropriately and safely only in the inpatient setting—as well as CMS's current process for removing procedures based on clinical criteria. The five criteria established by CMS to evaluate procedures for potential removal address the extent to which outpatient departments are equipped to provide the procedure to the Medicare population, whether the simplest procedure described by the code may be furnished in most outpatient departments, whether the procedure is related to codes that have already been removed from the IPO list, whether the procedure is furnished in numerous hospitals on an outpatient basis, and whether the procedure can be appropriately and safely furnished in an ASC. By annually applying these clinical and patient safety-oriented criteria on a case-by-case basis, CMS can ensure that the IPO list only covers those procedures that continue to be inappropriate for the Medicare population in the outpatient setting. Under the Proposed Rule, however, these clinical considerations would not come into play and Part A coverage would turn largely on the physician's expectations concerning the length of stay under the 2-midnight rule. ***The FAH opposes the proposed, arbitrary elimination of the IPO list as it would create inappropriate safety risks for Medicare beneficiaries, impose administrative burdens on physicians and hospitals, increase beneficiaries' financial burden, and erode the value of Part A coverage.***

The Proposed Rule identifies a handful of concerns with the IPO list, largely drawn from decades old comments provided in responses to CMS's original IPO list proposal.<sup>4</sup> These considerations—namely, deference to clinical judgment, the promotion of advances in surgical care, and intervening changes in the practice of medicine—do not support the elimination of the IPO list. Rather, patient safety, clinical considerations, administrative burdens, and beneficiary financial considerations all support the continued use of the IPO list.

***The IPO List Reduces Administrative Burdens Without Eroding Professional Judgment.*** As a general matter, the FAH agrees that the appropriate site of service for a particular procedure should typically be determined by surgeons and patients. But it does not

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<sup>3</sup> 65 Fed. Reg. 18,434, 18455 (April 7, 2000).

<sup>4</sup> 85 Fed. Reg. at 48,909 (citing 65 Fed. Reg. 18,442, 18,455).

follow from this general observation that physician judgment is undermined by recognizing those procedures that cannot be appropriately provided to Medicare beneficiaries on an outpatient basis and should not be payable under the OPPI. By way of example, CMS's long-standing recognition that the leg amputation described by CPT code 27592 (amputation, thigh, through femur, any level; open, circular (guillotine)) should only be provided to Medicare beneficiaries on an inpatient basis and paid under the IPPS simply reflects the invasive nature of the procedure and its indisputable and inherent risks. By categorically restricting coverage for these amputations based on the clinical evidence as inpatient only procedures, CMS appropriately advances patient safety without meaningfully limiting any physician's clinical judgment.

Meanwhile, the proposed elimination of the IPO list along with the continued operation of the 2-midnight rule would inappropriately result in level-of-care determinations based largely on the patient's expected length of stay and would increase the paperwork and administrative burdens where a patient is admitted for a short stay to undergo a procedure that should only be performed on an inpatient basis. When finalizing the 2-midnight rule in 2013, CMS stated its "belie[f] that inpatient-only procedures are appropriate for exclusion from the 2-midnight benchmark" and assured beneficiaries and providers that "inpatient-only procedures currently performed as inpatient 1-day procedures will continue to be provided as inpatient 1-day procedures" under the final rule.<sup>5</sup> Thus, the 2-midnight rule explicitly endorsed categorical inpatient treatment for procedures on the IPO list, preserving CMS's clinical determination that inpatient admissions are appropriate for these procedures in all cases. This approach ensures that procedures designated as inpatient-only can be provided on an inpatient basis *regardless of the expected length of stay*, unless and until CMS determines outpatient coverage is appropriate after considering the five clinical criteria for removal from the IPO list.

Under the Proposed Rule, however, CMS would effectively eliminate Part A coverage for these invasive 1-day procedures except in circumstances where the physician exercises his or her clinical judgment to order an inpatient admission "based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event" and the medical record supports these factors.<sup>6</sup> The inherent burden of establishing that an inpatient 1-day procedure qualifies for inpatient treatment on a case-by-case basis creates burdens for physicians and hospitals and risks the inappropriate migration of inpatient 1-day procedures to the outpatient setting. In addition, the factors used for these case-by-case determinations were developed against the backdrop of the IPO list and thus focus on patient-specific considerations without generally accounting for factors that govern inclusion on the IPO list (*e.g.*, the invasive nature of the procedure and the general need for postoperative care). In short, the elimination of the IPO list alongside the 2-midnight rule suggests that an inpatient admission for a 1-day procedure that was on the IPO list before its elimination would only be permissible based on case-by-case, patient-specific considerations.

This significant change increases the administrative and documentation burden associated with an inpatient admission for an invasive surgical procedure where medical advancements have reduced the average length of stay but significant risks remain, particularly in the Medicare

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<sup>5</sup> 78 Fed. Reg. 50,496, 50,947 (Aug. 19, 2013)

<sup>6</sup> 42 C.F.R. § 412.3(d)(3).

population (e.g., carotid stenting or transcatheter aortic valve replacement (TAVR)). The Proposed Rule provides no rationale for this substantial change in policy, nor does it address the provider burdens or patient risks inherent in shifting 1-day procedures currently on the IPO list to the outpatient setting except where case-by-case factors warrant inpatient admission.

The elimination of the IPO list would also risk eroding Part A coverage for skilled nursing facility (SNF) care following an inpatient procedure, increasing the risk to Medicare beneficiaries that experience post-procedure complications. At present, every Medicare beneficiary undergoing a procedure on the IPO list is admitted as an inpatient, in part to ensure that the patient receives adequate post-procedure monitoring for complications. If complications arise, the patient's inpatient stay might extend past three days, qualifying the beneficiary that is now at high-risk for adverse outcomes or readmission for SNF Part A coverage to ensure adequate and appropriate post-acute skilled nursing care. Without the IPO list, however, there's a risk that the physician will delay inpatient admission until *after* complications arise because, before that point, discharge prior to the second midnight might be possible. Although the time the patient spends in observation care is considered for purposes of the 2-midnight rule, it is not considered for purpose of the three-day qualifying hospital stay, such that a Medicare beneficiary admitted in this manner will not qualify for Part A SNF coverage unless his/her inpatient stay spans three midnights in addition to the time spent in observation. Not only does this erode the value of Part A SNF coverage, but it also places beneficiaries at risk for inadequate post-acute care and readmission.

In short, the necessity of an inpatient admission for a procedure on the IPO list should be beyond clinical question, but the Proposed Rule would require case-by-case scrutiny of these inpatient admissions when the patient can be discharged before the second midnight. This approach inappropriately focuses clinical judgment on the length of stay and case-by-case exceptions despite the categorical appropriateness of inpatient admissions for procedures included on the IPO list.

***The IPO List Does Not Operate to Impede Advancements in Surgical Care and Medical Advancements Do Not Support Elimination of the IPO List.*** The Proposed Rule draws heavily from the comments of “[s]everal major hospital associations”<sup>7</sup> in response to CMS’s proposal to create the IPO list in 2000. In those comments, hospital associations expressed concern that the IPO list would have an adverse effect on advances in surgical care.<sup>8</sup> In the intervening two decades, however, these concerns have not materialized. Rather, the FAH’s members have seen and contributed to significant advancements in surgical care, and CMS has in turn responded to these developments by annually evaluating procedures for removal from the IPO list based on clinical criteria, engaging stakeholders through notice-and-comment rulemaking. Through this process, CMS has sought to continually evolve the IPO list so that it reflects rather than limits advances in surgical care. Because the IPO list has largely evolved with medical advancements, it continues to focus on those procedures that are only appropriate to the inpatient setting in the Medicare population despite advancements in surgical care.

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<sup>7</sup> 65 Fed. Reg. 18,434, 18,442 (Apr. 7, 2000).

<sup>8</sup> 85 Fed. Reg. at 48,909 (citing 65 Fed. Reg. at 18,442).

The Proposed Rule suggests that, because “significant developments in the practice of medicine that have allowed numerous services to be provided safely and effectively in the outpatient setting, . . . the IPO list is no longer necessary to identify services that require inpatient care.”<sup>9</sup> These medical advancements, however, have not eroded the utility of the IPO list because, as the Proposed Rule documents, the IPO list has evolved with advances in surgical techniques and surgical care protocols so that the IPO list continues to be confined to those procedures that are only appropriate on an inpatient basis in the Medicare population notwithstanding these developments. For example, the IPO list includes brain biopsies, craniotomies, lung transplants, heart and lung transplants, and coronary artery bypass with six or more venous bypass grafts. The Proposed Rule does not indicate that clinical advancements allow for these procedures to be safely and appropriately performed in the outpatient setting. Nor could it—these procedures are extraordinarily invasive, necessitate significant postoperative care, and are performed on high-risk patients, making inpatient admission necessary and appropriate in all cases. Likewise, the Proposed Rule does not indicate that medical advancements render the 266 musculoskeletal-related procedures proposed for elimination from the IPO list in 2021 appropriate for the outpatient environment. Rather, the Proposed Rule bluntly removes procedures from the IPO list despite the fact that outpatient departments are not equipped to provide the services to the Medicare population, the simplest procedures described by the codes are not furnished in most outpatient departments, and the procedures are furnished in few or no hospitals on an outpatient basis.

***Elimination of the IPO List Erodes the Part A Benefit and Increases the Financial Burden on Beneficiaries.*** The elimination of the IPO list will also create financial burdens for Medicare beneficiaries because Medicare Part B coverage is associated with more significant cost-sharing obligations as compared to Part A coverage. Although the Part B coinsurance amount for a service is capped at the applicable Part A hospital inpatient deductible amount for that year, this cap does not adequately limit the beneficiary’s cost-sharing obligation for outpatient services. A beneficiary that had previously paid the entirety of his or her inpatient deductible amount for that year would still be faced with a coinsurance obligation for the outpatient procedure when s/he would have incurred no further cost-sharing obligations if the procedure had been performed on an inpatient basis. Likewise, payment of the maximum outpatient coinsurance amount for a procedure would not satisfy a beneficiary’s inpatient deductible obligation for a subsequent admission in the same year.

In addition, the outpatient cost-sharing limit applies on a service-by-service basis, so beneficiaries may incur coinsurance obligations up to the cap for *each* service. The Proposed Rule notes that most of the procedures on the IPO list would be assigned to a comprehensive APC (C-APC) upon removal, limiting beneficiaries to a single, capped coinsurance obligation for the C-APC.<sup>10</sup> But, even if each procedure is assigned to a C-APC, beneficiaries may still receive items and services that are separately payable when furnished with a C-APC (*e.g.*, a procedure assigned to a new technology APC) and thus may incur coinsurance obligations for multiple items and services. Furthermore, a Medicare beneficiary will incur outpatient coinsurance obligations associated with certain outpatient services furnished in the days prior to

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<sup>9</sup> 85 Fed. Reg. at 48,909-10.

<sup>10</sup> 85 Fed. Reg. at 48,910-11.

the outpatient procedure, when those services would have been included on the Part A bill under the three-day payment window policy and would have resulted in no further cost-sharing obligations if the procedure had been performed on an inpatient basis. Thus, the coinsurance cap and the use of C-APCs does not adequately limit Medicare beneficiaries' cost-sharing obligations for outpatient services, and the proposed elimination of the IPO list would expand Medicare beneficiaries' financial exposure and erode the value of their Part A coverage. These expanded cost-sharing obligations also operate to the financial detriment to Medicaid programs, which are responsible for the Medicare coinsurance obligations of dually eligible beneficiaries.

***CMS Lacks Sufficient Data to Assign Procedures on the IPO List to APCs.*** Although the Proposed Rule includes proposed APC assignments for 266 musculoskeletal-related services, it fails to provide any data or rationale for the proposed assignments. In past years, CMS has based APC assignments for procedures removed from the IPO list on the estimated costs derived from available claims data and the 50th percentile IPPS payment for the procedure without major complications or comorbidities to determine the appropriate APC assignment.<sup>11</sup> But the assignments proposed in Table 31 are not supported by any similar analysis or rationale, and without any explanation of the methodology for proposing APC assignments for these procedures that would be eliminated from the IPO lists, stakeholders cannot meaningfully comment on the proposed assignments. At a high level, however, the complexity associated with a number of the listed procedures would warrant the creation of new APCs (e.g., Level 7 or higher Musculoskeletal Procedure APCs).

***Implications of Elimination of IPO List on Alternative Payment Models (APMs).*** The Proposed Rule wholly fails to address how the elimination of the IPO list would impact episode-based and total cost of care models. The growing focus on and expansion of various APMs for Medicare benefits necessitates a clear and transparent plan for addressing the impact of removing procedures from the IPO list on these APMs. In commenting on the Proposed Rule, stakeholders cannot readily engage with CMS on the potential ramifications of removing entire categories of procedures from the IPO list as part of the phased elimination of the list because CMS has not provided any indication as to the extent to which any of the procedures would be expected to migrate to the outpatient setting. It may be that clinical considerations would preclude most of the procedures proposed for removal in CY 2020 from being performed in the outpatient setting on Medicare beneficiaries, which would limit any impact on APMs. But the Proposed Rule suggests that an unspecified number of these procedures could be performed in an outpatient session at an unspecified frequency. To the extent that any outpatient migration is reasonably expected, it is critical that CMS project the magnitude of the effect and propose necessary adjustments to episode-based and total cost of care models if, for example, it is expected that the shift will skew certain procedures toward beneficiaries in poorer general health and with higher risks for complications.

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<sup>11</sup> For example, in the 2020 OPSS Proposed Rule, CMS evaluated the estimated costs for CPT code 27130 (total hip arthroplasty) based on the available claims data and the 50th percentile for MS-DRG 470 against the geometric mean cost for the Level 5 Musculoskeletal Procedures APC series to explain the proposed assignment of the procedure to APC 5115. 84 Fed. Reg. 39,398, 39,460 (Aug. 9, 2019).

***Adverse Impact for Medicare Part C Beneficiaries.*** Finally, the elimination of the IPO list risks adverse impacts for Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, but the Proposed Rule fails to address the collateral harm to these beneficiaries or the associated increased burden and cost of coverage disputes. Although the IPO list was adopted as “a valuable tool for ensuring that the OPPI only pays for services that can safely be performed in the hospital outpatient setting,”<sup>12</sup> it also plays an important role in the Part C context, ensuring that MA organizations provide appropriate inpatient coverage for the invasive and risky procedures that warrant inclusion on the list. And where MA organizations deny inpatient coverage for a procedure that should only be provided on an inpatient basis, the IPO list promotes the efficient resolution of the resulting coverage dispute. ***Without the IPO list, however, it is likely that Medicare beneficiaries that elect Part C coverage will experience increased denials of inpatient coverage for invasive procedures that require intensive postoperative monitoring and care.*** As we have shared in previous comment letters on the MA Program, there has been and continues to be a significant trend among MA organizations of denying coverage and authorizations for inpatient admissions ordered by physicians and reclassifying them as outpatient observations stays. We are now seeing this practice expand to inpatient surgical admissions ordered by physicians and reclassified by MA plans as outpatient surgeries, even in cases where the patient stay crosses two midnights.<sup>13</sup> Elimination of the IPO list risks fueling this trend, jeopardizing the health of Medicare beneficiaries and saddling hospitals with the additional administrative burden of appealing denials and reclassifications for procedures that are not appropriately provided in the outpatient setting.

VI. Inpatient Procedures that Do Not Meet the Criteria for Removal from the IPO List Should Be Excepted from Medical Review Unless and Until Two Years After They Meet the Clinical Criteria for Removal (Part X.B.)

If CMS finalizes the phased elimination of the IPO list despite the concerns set forth above, the FAH urges CMS to modify its medical review exemption so that inpatient admissions for a procedure previously included on the IPO list continue to be exempted from medical review and referrals indefinitely or until two years after CMS determines that the procedure satisfies the clinical criteria for removal from the IPO list. CMS proposes maintaining the current 2-year exemption from certain medical review activities by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs), BFCC-QIO referrals to Recovery Audit Contractors (RACs), and RAC “patient status” reviews for procedures removed from the IPO list as part of the phased elimination of the IPO list.<sup>14</sup> This 2-year exemption period, however, was developed for procedures that CMS determined were clinically appropriate for the outpatient

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<sup>12</sup> 78 Fed. Reg. 75055 (Dec. 10, 2013).

<sup>13</sup> In the past, the FAH has requested that CMS require MA organizations to use the 2-midnight rule in determining patient status. The proposed elimination of the IPO list is particularly troubling against the backdrop of MA organizations’ failure to apply the 2-midnight rule, and the FAH is concerned that, without the IPO list, MA organizations will override physician judgment and patient choice to deny inpatient coverage for procedures that necessitate extended post-operative monitoring and should only be performed on an inpatient basis.

<sup>14</sup> 85 Fed. Reg. at 48,939.

setting, allowing providers time to update their billing systems and gain experience with respect to the newly removed procedures. Here, however, procedures are being removed from the IPO list as part of a phased elimination of the list, even if the procedures continue to be categorically inappropriate for the outpatient setting. For example, the leg amputation described by CPT code 27592 (amputation, thigh, through femur, any level; open, circular (guillotine)) is proposed to be removed from the list despite being clearly inappropriate for the outpatient setting.

In this context of the proposed phased elimination of the IPO list, any medical review of the removed procedures would create administrative burdens and costs for providers without any associated benefit to the Medicare Program or beneficiaries. ***Unless and until a procedure removed as part of the proposed elimination of the IPO list is determined by CMS to be safe and appropriate for Medicare beneficiaries in the outpatient setting, the exception from medical review should continue for that procedure. Furthermore, if and when a procedure is determined by CMS to be safe and clinically appropriate for outpatient delivery, providers should be given two years to update their billing systems and gain experience with respect to the newly removed procedures, consistent with CMS's past practice with respect to procedures removed from the IPO list based on clinical considerations.*** In the interim, an inpatient admission for a procedure on the IPO list should not be subject to patient status reviews and the admission should be categorically presumed to be appropriate based on CMS's prior determination that the procedure is only clinically appropriate when furnished on an inpatient basis.

#### VII. Specimen Collection for COVID-19 Tests (Part X.C.)

CMS established HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [covid-19]), any specimen source) during the PHE. HCPCS code C9803 is assigned to APC 5731- Level 1 Minor Procedures with a payment rate of \$22.98 for 2020 for the duration of the PHE. HCPCS code C9803 is conditionally packaged meaning that it will only be paid separately if it is the only service provided or it is billed with a clinical diagnostic laboratory test that is separately payable. The FAH recommends that CMS retain HCPCS code C9803 and its current APC assignment and status indicator beyond the COVID-19 PHE.

#### VIII. ASC Covered Procedures List (Part XIII.C.1.d)

***The FAH strongly supports CMS's proposal to continue to apply current policies and criteria set forth in 42 C.F.R. § 416.2 and 42 C.F.R. § 416.166 for updating the ASC Covered Procedures List (ASC-CPL) and opposes both alternative options for modifying the process and criteria for additions to the ASC-CPL.*** The current standards and exclusion criteria for the ASC-CPL appropriately prioritize patient safety while still allowing the ASC-CPL to evolve with advancements in surgical care, and they should therefore remain in place. Although ASCs can safely perform a growing array of surgical procedures without having the capacity to provide inpatient care in the case of complications and without having satisfied other hospital conditions of participation (or being licensed and accredited as hospitals), ASCs should not be treated as the equivalent of hospital outpatient departments. ***ASCs are not regulated as hospitals, and since November 29, 2019, ASCs have not been required to have written hospital transfer agreements***



*or hospital physician admitting privileges.<sup>15</sup> Thus, procedures that pose significant patient safety risks (e.g., procedures that generally result in extensive blood loss, that require major or prolonged invasion of body cavities, directly involve major blood vessels, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy) should continue to be excluded from Medicare coverage in ASCs to ensure that Medicare beneficiaries receive these services in a setting that allows for rapid intervention and elevation of the level of care in the case of life-threatening complications.*

A. Exclusion of Procedures on the IPO List from the ASC-CPL

The FAH strongly supports CMS's proposal to retain the exclusion of procedures designated as requiring inpatient care. As explained above, the FAH urges CMS to retain the IPO list as a critical patient safety measure, in which case the proposed amendment to 42 C.F.R. § 416.166(c)(6) would be unnecessary. If, however, CMS nonetheless eliminates the IPO list despite the concerns expressed by the FAH and others, the FAH would support CMS's proposed amendment to 42 C.F.R. § 416.166(c)(6), which would ensure that those procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020 would continue to be excluded from the ASC-CPL even after the elimination of the IPO list. The elimination of the IPO list is being proposed without regard for the clinical appropriateness of furnishing the services on the IPO list outside of the inpatient setting, and because the procedures removed during the proposed phased elimination of the IPO list continue to only be appropriate for Medicare beneficiaries in the hospital setting, the FAH supports continued application of the December 31, 2020 IPO list as an exclusion criterion for the ASC-CPL.

B. Exclusion Criteria for the ASC-CPL Should Remain in Place

Under both alternative options set forth in the Proposed Rule, CMS would retain the exclusion criteria under 42 C.F.R. § 416.166(c)(6) through (8), but would remove the exclusion criteria in 42 C.F.R. § 416.166(c)(1) through (5). The FAH strongly opposes removal of these exclusion criteria, which have been successfully applied for over a decade and have not impeded the expansion of the ASC-CPL to cover a growing list of complicated surgical procedures where permitted by advancements in surgical care. The five exclusion criteria at issue each target surgical procedures that inherently pose significant safety risks because ASCs do not have hospital resources on site to rapidly provide the higher level of care necessary in the case of complications. By way of example, § 416.166(c)(5) excludes surgical procedures that commonly require systemic thrombolytic therapy. These procedures pose significant patient risks that require rapid intervention in a hospital setting in the event of complications, including embolization and stroke. Despite significant advancements in surgical care since this exclusion criterion was finalized in 2007, the risks of systemic thrombolytic therapy continue to be significant, and the categorical exclusion of procedures requiring such therapy from the ASC-CPL continues to be appropriate. Likewise, the other exclusion criteria at issue—which cover surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, or are generally emergent or life-threatening in nature—should remain in place.

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<sup>15</sup> 84 Fed. Reg. 51,732, 51,738 (Sep. 30, 2019).

The Proposed Rule suggests that the concerns warranting adoption of these exclusion criteria have largely been addressed with the passage of time. It is true that significant advancements in medical practice, surgical techniques, and medical technology have permitted a growing list of procedures to be safely performed in an ASC setting, but this is largely because advancements have permitted a growing array of procedures to be performed in a manner that no longer triggers an exclusion criterion. For example, some procedures that previously required major or prolonged invasion of body cavities can now be performed laparoscopically and are no longer excluded under 42 C.F.R. § 416.166(c)(2). Thus, recent advancements in surgical care have minimized the extent to which procedures trigger an exclusion criterion, and these advancements do not call into question the enduring salience of the exclusion criteria in identifying procedures that continue to pose significant and inappropriate safety risks in an ASC setting. In fact, the Proposed Rule does not include any evidence indicating that the patient safety risks associated with procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy have been meaningfully reduced by advancements in medical care or provide any other rationale for eliminating these critical exclusion criteria.

In the Proposed Rule, CMS indicates that surgical advancements have allowed certain ASCs to safely perform procedures “involving major blood vessels,” suggesting that this criterion is therefore no longer relevant. The exclusion criterion at 416.166(c)(3), however, was never intended to be applied in a rigid manner, and in fact CMS explicitly opted to maintain flexibility and declined to adopt a defined list of “major blood vessels” in 2007. At that time, CMS stated its belief that “the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures.”<sup>16</sup> Subsequently, CMS used this flexibility to add certain coronary procedures to the ASC-CPL in its CY 2020 OPPI/ASC Final Rule. The Proposed Rule does not suggest that this criterion—applied in the context of the clinical characteristics of individual procedures—is no longer salient in assessing patient safety risks. Rather, it merely suggests that the rigid interpretation of this criterion—which was rejected in 2007 and has not been applied—would be inappropriate. Without any supporting rationale for eliminating the context-specific exclusion criterion at 416.166(c)(3), elimination of this exclusion criterion would be arbitrary and inappropriate.

Because the current exclusion criteria at 42 C.F.R. § 416.166(c), in conjunction with the general standards in 42 C.F.R. § 416.166(b), have allowed the ASC-CPL to evolve and expand with surgical advancements while ensuring that procedures that continue to pose significant patient safety risks are restricted to the hospital setting, ***the FAH strongly urges CMS to retain the existing criteria and standards for the ASC-CPL.*** In addition, ***the FAH opposes the addition of the 270 procedures proposed to be added to the ASC-CPL under the second alternative proposal in light of these standards and exclusion criteria.*** In particular, many of the procedures in Table 41 present significant patient safety concerns, arise in emergency situations, and would necessitate the rapid deployment of hospital resources in the event of complications. The Proposed Rule does not provide any rationale or evidence indicating that each of the 270 procedures at issue under the alternative proposal would not be expected to pose

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<sup>16</sup> 72 Fed. Reg. 42,481 (Aug. 2, 2007).

a significant safety risk to a Medicare beneficiary when performed in an ASC or that standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following any of these procedures. By way of example, the list includes repair of a blood vessel with vein graft in the neck (CPT 35231), intrauterine fetal transfusions (CPT 36460), ligation of a major artery in the neck (CPT 37651), and appendectomy (CPT 44950). Each of these procedures (and the procedures included in the second alternative proposal more generally) pose significant patient safety risks, and Medicare coverage for these procedures should remain confined to the hospital environment where a patient can receive inpatient care in the event of complications. At the very least, CMS should provide some explanation of why or how each of the listed procedures satisfy the criteria and standards in 42 C.F.R. § 416.166(b) and (c) so that stakeholders can understand the rationale behind the proposal and provide meaningful comment.

C. Proposed Additions to the ASC-CPL for CY 2021

In the CY 2021 Proposed Rule, CMS proposes to add total hip arthroplasty (THA) and ten other procedures to the ASC-CPL for CY 2021. ***The FAH opposes adding THA to the ASC list in light of clinical concerns, expanded beneficiary coinsurance obligations for ASC procedures compared to hospital outpatient procedures, and the risks of providing payment for THA in physician-owned ASCs that are not subject to physician self-referral restrictions.*** The Proposed Rule emphasizes the importance of ensuring that physicians and patients have the flexibility to choose an ASC as the site of surgical care, observing that many ASCs delayed elective procedures during portions of the COVID-19 public health emergency. The COVID-19 pandemic, however, has also impacted elective procedures performed in hospital outpatient departments, acutely depressing revenue. These COVID-19 impacts, however, are best addressed through relief packages like the CARES Act Provider Relief fund, as well as the waivers and flexibilities adopted by CMS over the course of the public health emergency. The question of whether THA should be payable under Medicare Part B in the ASC setting should be evaluated independently of the impacts of the COVID-19 pandemic. In addition, the value of patient and physician choice are tempered where providing ASC coverage for a procedure will *increase* beneficiaries' cost-sharing obligations and referring physicians with an ownership interest in the ASC are not subject to self-referral restrictions.

***Higher Coinsurance in an ASC than the Outpatient Department.*** Medicare's payment for THA in an ASC according to Addendum AA of the Proposed Rule will be \$8,923.98, which would result in a Part B coinsurance obligation of \$1,784.79. When THA is performed in a hospital outpatient department, however, the Medicare Part B coinsurance amount is capped under section 1833(t)(8)(C)(i) to the inpatient hospital deductible limit (\$1,408 in 2020). Thus, a Medicare beneficiary's cost-sharing obligation for a THA performed in an ASC would be \$376.79 more than if the procedure had been performed in a hospital outpatient department (based on the 2020 inpatient deductible amount). In addition, because Medicare's payment under the OPPS is determined under the comprehensive-APC methodology, Medicare packages payment of all ancillary services into the OPPS payment resulting in no beneficiary coinsurance beyond the inpatient deductible cap. However, in the ASC, Medicare would pay separately for ancillary services that are integrally related to the surgical procedure, potentially raising beneficiary out-of-pocket costs further. Beneficiaries, however, may not understand these critical payment differences and their impacts on cost-sharing obligations; in fact, many may

wrongly assume that they will enjoy cost savings by undergoing a complicated procedure in an ASC rather than in a hospital outpatient department.

***Physician Self-Referral Risks.*** The foregoing concerns regarding beneficiaries' cost-sharing obligations for invasive procedures like THA are compounded by physician self-referral issues in physician-owned ASCs. The Physician Self-Referral Law, 42 U.S.C. § 1395nn, governs physician referrals to an entity for designated health services where the referring physician (or an immediate family member) has a financial relationship with the entity. Outpatient hospital services are designated health services under the statute, but surgical procedures performed in an ASC are paid as part of a composite payment for a group of services and are not currently subject to the Physician Self-Referral Law.<sup>17</sup> As such, the Physician Self-Referral Law does not govern physician referrals of Medicare beneficiaries to an ASC owned by the physician for a surgical procedure. The FAH is concerned that the combination of expanded coinsurance obligations for THA in an ASC with the lack of a physician self-referral prohibition to an ASC places beneficiaries at risk. ***Until such time as CMS can resolve these issues to protect Medicare beneficiaries, the FAH remains opposed to adding THA to the ASC-CPL.***

IX. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program (Part XIV)

***The FAH supports the proposal to expand the review and corrections policy to apply to measures submitted via a web-based tool as well as chart-abstracted measures.*** For 2021 reporting, three OQR Program measures are submitted by hospitals to CMS via a web-based tool (OP-22: ED Left without being seen; OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; and the voluntary measure OP-31: Improvement in Visual Function within 90 Days Following Cataract Surgery). We agree that it is appropriate for hospitals to have an opportunity to review and correct data on these measures as well as any future measures that may be reported using a web-based tool. We also support the proposed technical changes to codify and update the OQR Program regulatory text at 42 CFR 419.46.

X. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years (Part XV)

***The FAH applauds CMS's recognition for the opportunity of a much needed refresh and appreciates the proposals aiming to ensure the methodology is transparent, understandable, with clear cut-points and targets, and accurately reflecting the quality of care provided in the facilities. Until this is achieved and the changes are implemented, however, the FAH urges CMS to suspend the Star Ratings from the Hospital Compare website.***

***The FAH supports the proposal to codify the Overall Hospital Quality Star Rating methodology through notice and comment rulemaking.*** Since their initial publication in 2016, the Overall Star Rating has been a prominent feature of Medicare's *Hospital Compare* tool (now *Care Compare*), and codification will improve the transparency of the underlying methodology to hospitals and other stakeholders. Moreover, the rulemaking process provides stakeholders an opportunity to make formal comment on the methodology used to calculate these ratings and to review CMS's response to all public comments.

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<sup>17</sup> 66 Fed. Reg. 923 (Jan. 4, 2001).

The Proposed Rule would make a number of changes to the methodology that has been used by CMS to date in calculating the Overall Hospital Quality Star Rating. As the FAH has previously commented, the star rating methodology should be transparent, understandable, have clear cut-points and targets, and accurately reflect the quality of care provided by hospitals. We appreciate that the CMS proposals are intended to address issues with the methodology that have been previously identified by hospitals. ***The FAH generally supports the proposed changes to the Overall Hospital Quality Star Rating, with the following specific comments and concerns.***

***The FAH supports using the most recently available data for calculating the Overall Star Ratings and does not support the proposal to use data that was made public during the previous year.*** CMS would codify that the Overall Star Ratings are published annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year. This rules out using the data that is newly made public concurrent with the star ratings. While we understand that CMS offers this proposal so that hospitals would have more time to study the underlying data before the star ratings are made public, the FAH believes that using the most recent data for the calculations is the more important priority. There is a built-in data lag on *Care Compare* as in some cases individual measures reflect performance from several years back; delaying use of newer data adds to the disconnect between the published data and current hospital quality performance. ***In addition, CMS should be consistent regarding when the Star Ratings are published each year and which data are used for the calculations.*** Hospitals should not be in the position of making assumptions and possibly being surprised if the timing changes from year to year. The expected timing should be made clear in the final rule, and any future changes should be shared well in advance through the QualityNet website and other regular communication channels.

***In keeping with our previously stated principles, the FAH strongly supports the proposal to eliminate use of the Latent Variable Model (LVM) when calculating measure group scores.*** The LVM has resulted in Star Ratings that change in ways that cannot be predicted by a hospital's underlying performance and therefore can be difficult to explain to anyone unfamiliar with the details of the LVM. Use of a simple average to calculate measure group scores will be easily understood and will allow hospitals to anticipate changes in the Star Ratings based on changes in performance on the underlying quality measures.

***The FAH supports the proposed continued inclusion of CAHs and the future addition of Veterans Health Administration (VHA) hospitals in the calculation of the Overall Star Rating.*** The CAHs report quality data voluntarily, and have the opportunity to request their data not be publicly reported (and therefore unavailable for use in the Overall Star Rating calculation) or that the assigned star rating not be posted on *Hospital Compare*. Future policymaking regarding VHA hospitals should consider how comparable these facilities are to the bulk of hospitals for which quality performance is displayed.

***The FAH supports the proposed peer grouping of hospitals, although CMS should work to educate the public on how to interpret Star Ratings that are calculated by peer group.*** Assessing hospital performance by national peer group is useful to hospitals for purposes of quality improvement because it allows for comparisons of similar facilities. However, Medicare

beneficiaries and other consumers are more likely to compare hospitals within their geographic area. If these hospitals happen to fall into different star rating peer groups a direct comparison of star ratings may not be appropriate, and the public will need to be guided on how to use the star ratings in comparing hospitals. CMS has suggested that for stakeholders the hospital summary score available in the downloadable database could serve as the basis of a national comparison because it is calculated before hospitals are sorted into peer groups, but this would not be a practical solution for members of the public who seek to compare hospitals.

***CMS should continue to assess how the peer groups are defined.*** Ideally, the peer groupings used to calculate the Overall Star Rating would be refined and reflect differences in the types of services provided by hospitals. Under the proposal, CMS estimates using the January 2020 data release that 73 percent of hospitals fall into one of the three peer groups (hospitals with scores for all five measure groups), which limits the value of peer grouping. In addition, CMS reports that CAHs comprise about half the hospitals in the peer group for hospitals with three measure group scores, noting that the proposed peer grouping approach will not be finalized if CAHs are not included. Because CAHs report quality measure data voluntarily and have the option of suppressing the public reporting of their data prior to calculation of the star rating, CMS should address how it will determine whether a sufficient number of CAHs have reported data that can be used for the star ratings calculation for a year.

***The FAH believes that the readmission measure group should be scored in the same way as these measures are scored for the Hospital Readmissions Reduction Program (HRRP).*** Under the proposal, for purposes of the Overall Star Rating, CMS would stratify the readmissions measure group scores by the hospital's proportion of Medicare and Medicaid dual eligible patients using the same quintiles used in the HRRP. We agree that it is appropriate that there be consistency in the scoring for these two purposes. However, the June 2020 report of the HHS Assistant Secretary for Planning and Evaluation recommends replacing stratification by dual eligibles when scoring readmission measures with separate public display of a hospital's performance on the readmission measures for patients who are dual eligibles and others. If in the future, CMS eliminates or changes the stratification approach used in the HRRP, a parallel change should be made in the calculation of scores for the readmission measure group in the Overall Star Rating.

Other elements of the proposed methodology include reducing the number of measure groups from seven to five; continuing the existing scheme for weighting measure group scores (22 percent each for Mortality, Readmissions, Patient Safety and Patient Experience and 12 percent for Timely and Effective Care); continuing policies for the measure selection and exclusion, and continuing the use of k-means clustering for setting the cut-points for the five star levels. The FAH does not oppose these proposals.

***Once use of the new methodology is operationalized, CMS should continue to work with stakeholders to identify additional improvements that may be needed in the future.*** The FAH appreciates that the proposed regulatory text identifies responsiveness to stakeholder input as a goal along with transparency in methods, use of scientifically valid methods and alignment with *Care Compare*. As our hospitals gain experience with the new methodology, further

changes may be offered for ensuring that the Star Ratings reflect true differences in hospital quality performance.

***The FAH continues to believe that the patient safety composite measure PSI-90, or its components measures, should not be included in the Overall Star Rating and urges CMS to remove them from quality programs.*** The PSI-90 measures use claims data to identify patients who have experienced a safety event. While useful to identify patients whose treatment experience requires further investigation, it is not a reliable reflection of a patient safety event and as such could be misleading. This lack of reliability in the identification of a safety event renders the PSI-90 measure a poor measure to use in public reporting or pay-for-performance programs.

XI. Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department Services (Part XVII)

***The FAH strongly advises that CMS reconsider its proposal regarding prior authorization for certain hospital outpatient services given the potential impact on payment to providers and the health and welfare of patients that would result from delays in receiving needed medical services.***

***CMS has equated increases in utilization above the national average as being unnecessary without fully exploring the reasons for the increase.*** While CMS may have looked for external factors that may explain the increase in utilization, it has not done a sample medical review to determine whether increases are necessary or unnecessary. If CMS were to do a sample medical review and find that the large majority of these services were necessary, prior authorization would not be justified. Prior authorization would only be imposing an unnecessary burden on hospitals, physicians and patients for medically necessary services. Medical review could also show whether increases are largely justified but that there are particular physicians or other providers responsible for unnecessary increases where targeted prior authorization may be merited. Moreover, the Proposed Rule wholly fails to address whether concerns regarding increases in utilization of outpatient department services continue to be salient in the midst of the COVID-19 public health emergency. In response to the pandemic, the volume of hospital outpatient services has declined as hospitals and patients delay or cancel many elective procedures. Pre-COVID-19 utilization data does not reflect the vastly changed circumstances in our health care delivery system, and it is inappropriate to use this data to impose new prior authorization requirements.

As we indicated in comments on the CY 2020 OPPTS/ASC Proposed Rule, we remain concerned that the prior authorization policy could potentially delay treatment and seriously jeopardize a beneficiary's health or ability to regain maximum function. These risks are particularly acute in the context of the COVID-19 pandemic, where elective procedures are already subject to temporal constraints based on changes in the community transmission rate and other volatile public health factors in addition to the patient's clinical condition. Further, the FAH believes that before expanding a prior authorization requirement to additional services, CMS should also evaluate the implementation and impacts of the current prior authorization requirements for select procedures. If the large majority of prior authorization requests for those services subject to the requirement in CY 2020 were approved, this

evidence would suggest that the prior increase in service utilization did not represent unnecessary growth in service volume. Such results may also indicate that any diminution in the rate of growth for these services reflects the policy's adverse impact on beneficiary access to necessary services rather than the desired reduction in unnecessary service volume.

***Further, the burdens that prior authorization imposes with no clear benefit is inconsistent with the Administration's "Patients Over Paperwork" initiative.***

The FAH reiterates the position we took last year that the policy will place providers in an untenable position of potentially providing the needed services immediately, without authorization, and risking payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, CMS's proposed policy would force significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations.

A. Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department Services (Part XX)

In the CY 2021 OPPTS/ASC Proposed Rule, CMS proposes to establish prior authorization for an additional 2 categories of services: 1) Cervical Fusion with Disc Removal; and 2) Implanted Spinal Neurostimulators. (85 FR 49028). Under the prior authorization process, hospitals would request provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. The prior authorization request would have to include all relevant documentation necessary to show that the service meets Medicare coverage, coding and payment rules. A claim submitted for a service subject to a prior authorization requirement that has not received a provisional affirmation of coverage would be denied. Additionally, a service for which provisional affirmation was received may still be denied, based on technical requirements or information not available at the time that affirmation was provided. Provisional affirmation or non-affirmation decisions would be made within 10 business days (2 business days in the case of an expedited review request where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function). A non-affirmation decision would not be appealable.

A provisional affirmation denial would include any claims associated with the service, including anesthesiology services, physician services, and/or facility services. CMS claims section 1833(t)(2)(F) of the Act as its authority for prior authorization. While the FAH believes it is questionable whether section 1833(t)(2)(F) of the Act provides authority to apply prior authorization at all to any services, it is very clear that this authority is only limited to "the prospective payment system established by the Secretary in accordance with this subsection" (e.g. the OPPTS). The Secretary has no authority to apply prior authorization to anesthesiology services and other physician services that are paid under section 1848 of the Act.

Cervical fusion and implanted spinal neurostimulators are procedures that are often provided to patients with chronic intractable pain. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review



payments under the OPPI for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. ***CMS's prior authorization policy is in direct contradiction with the spirit of the SUPPORT Act in that it diminishes incentives to provide non-opioid treatment alternatives.*** Prior authorization may result in delays in the provision of these services, which could mean that the patient will instead take powerful opioids to control pain rather than using a non-opioid alternative treatment. In light of the opioid crisis—which the Secretary has determined to be a nationwide public health emergency, the FAH has significant concerns about subjecting these particular procedures to medical review.

For implantable neurostimulators, CMS indicates that it “fully accounted for changes that occurred in 2014 related to electrodes being incorporated into the 63650 code” when accounting for the service volume change. The FAH does not know to what this sentence refers. Our review of CPT and other sources does not show any coding changes for CPT code 63540 in 2014. This review shows this code as being unchanged since 1994.

In the Proposed Rule, CMS notes that the average annual increase in volume was 17 percent for implanted spinal neurostimulators between 2016 and 2018. While the FAH's analysis of Standard Analytic File (SAF) data validates this trend, our review of the data also shows utilization increasing 6 percent in 2013, 2 percent in 2014, decreasing 4 percent in 2015 and decreasing 7 percent in 2019. It is not clear why the growth rates for implantable spinal neurostimulators show significant increases in the 2016 to 2018 period but they appear to be atypical compared to the 3-year period preceding 2016 and the one year following 2018. Such an atypical period of growth between 2016 and 2018 suggests something was occurring during this time rather than that growth was unnecessary and should be subject to prior authorization. We encourage CMS to do a more detailed medical review of the utilization of these procedures to determine why growth in the 2016 to 2018 period was atypically high.

With respect to cervical fusion, CMS indicates that the use of code 22551 “almost tripled” in 2012. CPT code 22551 was removed from the IPO list as of January 1, 2012 (76 FR 74355) which would explain its utilization growth for that year and subsequent years as these procedures transitioned to the outpatient setting consistent with CMS policy. CPT code 22552 remained on the IPO list until 2016 but, because it is an add-on-code, CMS's policy means that it would have been line item denied, since the payable/primary procedure was not restricted to the inpatient setting even though add-on codes are not paid extra under the OPPI. This policy makes no sense. If a base code can be done outpatient, its add-on codes should also be permissible on an outpatient basis.

Beginning in 2016, CPT code 22552 was removed from the IPO list and is part of a complexity adjustment for C-APCs (80 FR 70468 and 80 FR 70331 respectively). Large growth in combined utilization for CPT codes 22551 and 2252 occurred just one year later in 2017 which is clearly associated with the add-on code utilization suddenly being allowable when previously it may have been performed as an outpatient service but denied as inpatient only on an outpatient claim. It is clear that it is CMS policy and not unnecessary utilization that is resulting in the high growth rate for these procedures in the hospital outpatient setting. For this

reason, the FAH believes procedure codes 22551 and 22552 should not be subject to prior authorization.

B. Patient Health and Well-Being Will Be Affected by Delays in Medical Care

CMS indicates that provisional affirmation will be provided within 10 days of a request and 2 days where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. The FAH is concerned about the potential for CMS's policy to delay treatment for 10 days where the request may not meet the requirements for expedited review but the patient is still suffering from a painful and debilitating condition such as chronic intractable pain. ***In situations where a delay in receiving medical care could seriously jeopardize the beneficiary's life, health or ability to regain maximum function, any responsible health care provider will furnish the needed services immediately and not wait 2 days for a response from Medicare.*** Yet, absent the prior authorization, CMS's proposed policy would deny payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, CMS's proposed policy would force significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations.

XII. Revisions to Laboratory Date of Service (DOS) Policy (Part XVIII)

Protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) laboratory tests are not considered molecular pathology tests subject to the CMS packaging policy. However, several stakeholders have suggested that they believe the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service. CMS proposes to modify the lab date of service rule to apply the same date of service to these tests as molecular pathology tests and ADLTs. This proposed revision to the laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs to bill Medicare directly for those tests instead of seeking payment from the hospital when the service is not-packaged and the DOS rule is met. The FAH supports this policy.

XIII. Physician-Owned Hospitals (Part XIX)

***The FAH strongly opposes CMS's proposal to effectively remove all limits on expansion by physician-owned "high Medicaid facilities," including the frequency with which such a facility can request a capacity expansion; the caps on the number of operating rooms, procedure rooms and beds that can be approved; and the requirement that expansion must only occur on the main campus. We also would strongly oppose any removal or limitation of the opportunity for community input on expansion requests from high Medicaid facilities.***

CMS projects in the Proposed Rule that only one physician-owned hospital (POH) per year will request an expansion exception on the grounds that it is a high Medicaid facility. CMS further believes the proposal is unlikely to lead to more frequent expansion exceptions. This suggests that CMS believes the proposal is narrow and likely to have little impact. We disagree.

For multiple reasons, the proposal is much broader than purported in the Proposed Rule and its impact will far surpass only Medicaid patients, while opening the door for significant gaming by POHs and thus undermining Congressional intent to strictly limit POH expansion.

The FAH and the American Hospital Association (AHA) engaged DeBrunner & Associates to analyze the Medicare cost report data for POHs, including high Medicaid facilities. Overall, the analysis shows that there are at least 14 POHs that could qualify as a high Medicaid facility based on the most recent Medicare cost report data (FY 2016-2018) and another six POHs that are on the cusp of qualifying (i.e., they met the high Medicaid requirements in FYs 2017 and 2018 and thus could qualify depending on their FY 2019 data). Still four other POHs met the high Medicaid requirements in FY 2018 and thus could qualify depending on their FYs 2019 and 2020 status.<sup>18</sup> In total, the analysis revealed 24 facilities that either currently – or soon could – qualify as a high Medicaid facility and thus benefit from the broad expansion policies CMS put forth in the Proposed Rule.

The analysis also reveals the low bar needed for some facilities to meet the high Medicaid requirements. For example, one of these “cusp” POHs had the highest Medicaid discharge percentage in the county at a mere 3.3 percent in FY 2018. If it maintained this “high” Medicaid status for only one more year (FY 2019), it would qualify for an expansion exception request. Moreover, its uncompensated care costs as a percentage of its overall operating costs in FY 2018 are minimal at 1.1 percent, and its occupancy rate is under 45 percent. This particular POH clearly is not critical for ensuring access to care for Medicaid patients, yet it could request to expand without limits under CMS’s proposal. This is clearly not what Congress had in mind when it established the narrow “high” Medicaid facility exception to its overall policy to strictly limit the expansion of POHs.

The FAH discusses our specific key concerns with the proposal below.

### ***The Proposal Creates Incentives to Game Opportunities to Become High Medicaid Facilities***

The proposal creates incentives for facilities to “game the system” by creating opportunities to become a high Medicaid facility, by meeting low thresholds. Under the proposal, there no longer would be a limit on the percentage increase of a high Medicaid facility’s baseline number of operating rooms, procedure rooms, and beds. In addition, POHs would no longer be limited to expansion on their main campus and thus could expand beyond to off-campus locations as well.

This will provide POHs with a significant incentive and the ability to game the system. For example, without the main campus limitation, a high Medicaid facility could merge with or purchase a non-POH, which could be operated as a “remote location” of the POH and share its Medicare provider number, thereby greatly increasing the number of operating rooms, procedure rooms, and beds.

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<sup>18</sup> DeBrunner & Associates analysis of FFY 2016-2018 Medicare Cost Reports, September 2020. 214 Physician owned hospitals were identified for purposes of this analysis.

***Further, if as a result of such a merger the provider would lose its status as a high Medicaid facility due to a dilution of the provider's percentage of Medicaid admissions, the provider would still be able to engage in the expansion because there is no provision in the statute or the regulations that requires a facility to maintain its "high" Medicaid status or that permits a rollback of an approved expansion, once granted.*** By the same token, in any circumstance, even absent a merger, once the high Medicaid POH secures an expansion, the high Medicaid requirement disappears. ***The facility could become the lowest Medicaid provider in its county, and it would still retain the full complement of expansion beds, operating rooms and procedure rooms.***

Therefore, a POH would have an incentive to become a high Medicaid facility simply to take advantage of the expansion exception, but no incentive to maintain their "high" Medicaid status after receiving the exception. We note that the ability to achieve this status is enhanced in states that have expanded their Medicaid programs under the *Affordable Care Act* (ACA). Illustrating the disincentive to maintain the designation list, the DeBrunner & Associates analysis identified a POH (POH A) that qualified as a high Medicaid facility when its expansion exception request was approved by CMS, but which is no longer the high Medicaid facility in the county.

#### ***There is Not a High Bar to Qualifying as a High Medicaid Facility***

There is ample opportunity for gaming the system, as discussed above, because in many counties there is not a high bar to qualifying as a high Medicaid facility. ***There is no statutory requirement that a high Medicaid facility in fact serve a high number of Medicaid patients. Instead, a high Medicaid facility is one that simply has a higher percentage of Medicaid admissions than the other hospitals (which may be very few in number) in the same county.*** SSA § 1877(i)(3)(F). A 2016 study found that, on average, only 2.2 percent of patients admitted to POHs are Medicaid patients, a percentage that is less than 1/5<sup>th</sup> of the percentage of Medicaid patient admissions to non-POHs.<sup>19</sup>

More specifically, ***the DeBrunner & Associates analysis shows, for example, one POH that qualifies as a "high" Medicaid facility with a FY 2018 Medicaid discharge percentage of only 1.9 percent*** (POH B). Yet, that 1.9 percent constitutes the highest percentage of Medicaid patients in the county, ***a county with only two facilities***. This suggests that this county treats virtually few, if any Medicaid patients, and that Medicaid patients likely are treated in neighboring counties. The analysis shows that, with respect to POH B, ***hospitals in the neighboring counties treat significantly higher percentages of Medicaid patients. These facilities have FY 2018 Medicaid discharge percentages of approximately 13 percent, 15 percent, and 22 percent, which points to the distinct possibility that POH B treats patients for which it receives more lucrative payment (patient cherry picking), which results in neighboring county hospitals having to provide access to Medicaid patients – exactly the behavior Congress intended to curtail when it enacted strict limits on POHs.***

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<sup>19</sup> Dobson & Davanzo, Analysis of FY 2018 MedPAR Data, September 2020.

Moreover, the data shows that POH B, especially in comparison to hospitals in neighboring counties, has significantly lower rates of uncompensated care costs as well as discharges with emergency room services, 2.3 percent and 11.4 percent, respectively.<sup>20</sup> In contrast, the neighboring county hospitals have uncompensated care costs as a percentage of overall operating costs ranging from 5 percent to 11 percent and discharges with emergency room services ranging from 63 percent to 92 percent. As evidenced by the data, permitting POH B an uncapped expansion would not promote access to care for Medicaid patients. And, as discussed above, once a high Medicaid facility's exception request is granted, there is no requirement for the POH to maintain that status, as illustrated by POH A.

***The examples above undermine any argument that CMS's proposed policy reversal is intended to support hospitals serving a high number of Medicaid patients. Rather the policy reversal could operate to support POHs that do not serve large numbers of Medicaid patients or those that meet a relatively "high" threshold but do so for a relatively short period of time.***

Further, since "high" Medicaid facilities treat all patients, and may in fact treat very few Medicaid patients, as in the POH A example above, the proposal if finalized would allow POHs to expand with regard to all patients, not just Medicaid patients. As such, a POH that doubles its capacity from, for example, 75 to 150 beds, could fill those additional beds and, indeed, all the facility's beds, with non-Medicaid patients. The data show that the existing POHs whose expansion exception requests have been approved by CMS generally doubled in size under the approved request and this could increase exponentially under the proposal since it removes all limits on expansion and does not require that such expansion facilitate or maintain the POH's continued service to Medicaid patients.

#### **There Are No Limits on "High" Medicaid Facility Expansion and Off-Campus Facilities**

The FAH has grave concerns that the proposal would remove all limits on the ability of a high Medicaid facility to expand, including permitting unlimited off-campus facilities. ***Once a hospital meets the definition of a high Medicaid facility (even if temporarily) and its exception request is granted, it could expand without any limitation and without any requirements for when that expansion would occur.*** A POH could expand to double or triple or more in size, through both an on-campus expansion or the purchase or building of an off-campus facility (or multiple off-campus facilities). Further, the POH could undertake and complete that expansion sometime in the distant future after it no longer qualifies as a high Medicaid facility.

Further, there are no limits on service line expansion. Therefore, ***a POH could choose to build or purchase an off-campus facility of any size, entirely dedicated to hips and knees or other specific service lines and with no Emergency Department, with devastating consequences for neighboring full-service community hospitals.*** Nothing in the proposal would prevent a proliferation of these new POHs.

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<sup>20</sup> DeBrunner & Associates analysis of FFY 2016-2018 Medicare Cost Reports, September 2020.

### **There Are No Guidelines for CMS to Deny or Amend an Exception Request**

The FAH is concerned that if CMS removes all limits on expansion for high Medicaid facilities, the Agency eliminates its discretion to deny requests for expansion, as the proposal will remove any requirements for approving or denying such requests, and the underlying regulations do not provide any guidelines for such actions. This raises the question of whether a denial by CMS could be legally challenged by a POH as “arbitrary and capricious” and is another factor that could incent expansion exception requests, as there may not be any reasonable basis for denials of these requests.

### **CMS Has Not Presented a Cogent Rationale or Medicare or Medicaid Program Benefit for Reversing Its Longstanding High Medicaid Facility Policy**

The Proposed Rule does not articulate a need for the proposed policy reversal nor any benefit to the Medicare or Medicaid program. If finalized, the proposal will eviscerate Congress’s intent to place strict limits on the expansion of POHs, with only imagined benefits to the Medicare or Medicaid programs. In fact, ***the proposal is more likely to harm these programs by increasing the number of POHs despite years of independent data showing that self-referrals to physician-owned hospitals result in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns at significant cost to patients and the Medicare program.***

Congress purposefully put tight restrictions on the growth of POHs in the *Affordable Care Act* (ACA), and the exceptions to the limits on expansion of POH operating rooms, procedure rooms and beds were intended to be very clearly and carefully circumscribed. ***CMS has not identified any access to care concerns for Medicaid recipients that have been caused by the present limits on POH expansion nor identified any instances in which POHs would increase the number of Medicaid patients they serve but for the limits on expansion. In short, the proposal contravenes congressional intent and serves no public policy purpose.***

The lone commenter to the CY 2012 OPPS Proposed Rule that addressed the proposal for uniform requirements/limitations in the exception on expansion stated that applying parallel requirements to both “applicable hospitals” and “high Medicaid facilities” would result in an efficient and consistent process. CMS responded “[w]e agree with the commenter regarding our application of parallel requirements.” 76 *Fed. Reg.* 74,524 (Nov. 30, 2011). The FAH agrees with the 2012 commenter and CMS’s response that the same requirements and limits on expansion should apply to POHs applying for an exception regardless of whether they are applying under the “applicable hospital” exception or the “high Medicaid facility” exception. The FAH also believes the current policy has worked as Congress intended and should be maintained by CMS.

CMS has not offered a rational explanation for the sudden reversal of its longstanding position. To the contrary, CMS states in the Proposed Rule that it continues to believe that the “current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress’ intent to prohibit expansion of physician-owned hospitals generally.” 85 *Fed. Reg.* 49,038 (Aug. 12,

2020). The only rationale proffered in the Proposed Rule for the change in policy is that CMS believes that its current regulations “impose unnecessary burden on high Medicaid facilities.” But CMS does not provide any specifics supporting this statement. For example, ***CMS does not point to any particular high Medicaid facility that has been or would be harmed, or describe the nature of the alleged “burden,” or how the Medicare program or Medicaid patients would be better served by so radically relaxing restrictions on expansion by high Medicaid facilities.*** As discussed previously, CMS has not issued guidelines that even identify “high” Medicaid facilities – just facilities that are higher than other hospitals located in the same county.

While CMS ties its proposal to the *Patients over Paperwork* initiative, this connection is tenuous at best as CMS also states that it does not believe that the proposal would result in any change in burden under the Paperwork Reduction Act. Specifically, without explanation, the Proposed Rule says CMS does not anticipate any change in the annual number of respondents, that more frequent expansion requests would be unlikely, and that it is not changing the information being collected. The data we examined strongly suggests otherwise. As such, there is no clear proposed benefit to CMS’s proposed change in policy. While administrative simplification is suggested as the reason for this proposed policy change, the only clear impact of the proposal if finalized will be to undermine Congress’s goal of limiting Medicare utilization by POHs.

We also note that CMS projects that only one POH per year will request an expansion exception on the grounds that it is a high Medicaid facility. This raises the question as to whether the proposal is merely meant to benefit a few specific hospitals, which is not a rational basis for establishing such a broad-based policy change.

### **CMS Should Maintain the Requirement for Community Input**

CMS is considering whether it should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities. ***The FAH strongly opposes any removal or limitation of the opportunity for community input on expansion requests from high Medicaid facilities.*** Although CMS states in the Proposed Rule that obtaining community input “could” delay or add complexity to the approval of an expansion request, it does not identify any instances in which this has occurred.

We also note that CMS discusses that elimination of the community input requirement could in fact *cause* a delay and/or *increase* complexity because CMS would have to independently verify the data provided by the POH. This counterintuitive logic highlights the very reason why community input is essential – and foundational to the notice and comment process underlying public rulemaking. It is critical for maintaining a transparent process that provides CMS with the necessary data for verifying or disproving a requestor’s high Medicaid facility status as well as State licensure for the requested expansion.

***Local community hospitals are not only best able to comment on the need for expansion, but also are arguably the only opportunity for CMS to verify that a POH requesting an expansion exception is an eligible applicant.*** In conducting the analysis referenced herein, DeBrunner & Associates found that a not insignificant percentage of the

available county data was inaccurate (in some cases due to an incorrect spelling of a county name – a seemingly simple error but with enormous consequences for decision-making) and thus it may be difficult to determine whether a POH does in fact have the highest Medicaid admissions percentage in the county. In these cases, it is imperative that CMS maintain the public comment process to hear from other community hospitals and verify the eligibility of POH's applying for this exception and associated expansion.

For the reasons above, the FAH strongly opposes CMS's proposal and urges its withdrawal.

\*\*\*\*\*

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil, Executive Vice President, at 202- 624-1529.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Speil", with a stylized flourish at the end.





October 7, 2021

MANISH SINGH, MD, CEO  
DHR HEALTH BROWNSVILLE  
4750 N EXPRESSWAY 77  
BROWNSVILLE, TX 78526

**Re: Application to Operate a General Hospital Deficiency Notice**

Dear Dr. Singh:

This is to serve as notification that we are in receipt of the Multiple Location Initial General Hospital License Application for DHR Health Brownsville. The application and submitted documents have been reviewed. We are unable to process the application until the following documents are corrected /received:

- **Application type** – Please note: If the waiver is not approved, I will not be able to license this location as a multiple location of license #007971 since it is located 47.24 radial miles from the parent hospital and the licensing rules only allow for a 30-mile radius.
- **Ownership Information (Page 1, Section 2)** – According to our records, the entity tied to tax ID 74-2802643 is Day Surgery at Renaissance Ltd. If this has changed, please provide the Certificate of Amendment issued by the Secretary of State.
- **Hospital Services (Page 2, Section 4)** – Please remove "Medical". This service is reserved for Special Hospitals.
- **Accreditation (Page 3, Section 8)** - Please submit the most recent certificate or letter of accreditation from the Joint Commission issued to Doctor's Hospital at Renaissance.
- **Fire Safety Survey (Page 3, Section 11)** – Please submit the approved Fire Safety Survey once received. Reference 25 TAC §133.23(b)(1)(B), "a copy of a hospital fire safety survey indicating approval by the local fire authority in whose jurisdiction the hospital is based."

- **PTP/MOT (Page 4, Section 12)** – Pending approval from Janae Robinson. Janae can be reached by email at [janae.robinson03@hhs.texas.gov](mailto:janae.robinson03@hhs.texas.gov).
- **Pre-survey Conference (Additional Requirement)** – Please contact the Health Facility Compliance Office in San Antonio at [jeanette.salinas@hhs.texas.gov](mailto:jeanette.salinas@hhs.texas.gov) regarding your facility's pre-survey conference. Please reference the hospital licensing rules found at 25 TAC §133.22 (c), "Pre-survey conference. The applicant or the applicant's representative shall attend a pre-survey conference at the office designated by the department." Please send at least one individual who is listed on the application and who will be in charge of day-to-day operations.
- **Final Architectural Inspection (Additional Requirement)** – Submit the Final Architectural Inspection form upon completion of architectural inspection. For questions regarding this requirement, contact the Architectural Review Unit at [AskARU@hhs.texas.gov](mailto:AskARU@hhs.texas.gov).

Please submit the requested documents or make the required changes on the application along with a date and initial alongside the corrections. Only submit pages requiring corrections or documents needed, do not resend entire packet. Amendments can be emailed to Angela Arthur at: [angela.arthur@hhs.texas.gov](mailto:angela.arthur@hhs.texas.gov).

Sincerely,



Angela Arthur  
License & Permit Specialist IV  
Regulatory Services Division  
Health Facility Licensing



## Application for a License to Operate a Multiple Location General or Special Hospital

Service Code: 529201039  
Dept. ID: ZZ101 Fund: 152

Name of Main Hospital: Doctors Hospital at Renaissance, Ltd.	Main Hospital License No.: 007971
Multiple Hospital Designation: <input checked="" type="radio"/> General <input type="radio"/> Special	
Multiple Hospital Application Type: <input checked="" type="radio"/> Initial <input type="radio"/> Change of Ownership <input type="radio"/> Relocation	
Projected Opening Date or Projected Change of Ownership Effective Date: December 1, 2021	
Architectural Project No.: 17065	
Hospital within a Hospital? <input type="radio"/> Yes <input checked="" type="radio"/> No	

### Section 1 – Hospital Information

Name Hospital will be Doing Business As (D/B/A) or Assumed Name: DHR Health Brownsville				
This is the name that will appear on the license and should match advertisements and signage of the hospital.				
Street Address: 4750 N Expressway 77	City: Brownsville	State: TX	ZIP Code: 78526	County: Cameron
Mailing Street Address or P.O. Box No. (if different):		City:	State:	ZIP Code:
Area Code and Phone No.: (956) 362-7469		Area Code and Fax No.: (956) 362-7371		

### Section 2 – Ownership Information

Legal Name: Doctors Hospital at Renaissance, Ltd.																	
This is the name of the direct owner legally responsible for the day-to-day operation of the hospital, whether by lease or ownership.																	
Mailing Street Address: 5501 S McColl Rd.	City: Edinburg	State: TX	ZIP Code: 78539														
EIN No.: 74-2802643	Area Code and Phone No.: 956 362-8677	Email Address: legalcounsels@dhr-rgv.com															
Status: <input checked="" type="radio"/> Profit <input type="radio"/> Nonprofit	Type of Ownership: <table border="0"><tr><td><input type="checkbox"/> City</td><td><input type="checkbox"/> Hospital District/Authority</td></tr><tr><td><input type="checkbox"/> Corporation</td><td><input type="checkbox"/> Limited Liability Company (LLC)</td></tr><tr><td><input type="checkbox"/> County</td><td><input type="checkbox"/> Limited Liability Partnership (LLP)</td></tr><tr><td><input type="checkbox"/> Hospital</td><td><input type="checkbox"/> Limited Partnership (LP)</td></tr><tr><td><input checked="" type="checkbox"/> Limited (LTD)</td><td><input type="checkbox"/> Partnership</td></tr><tr><td><input type="checkbox"/> Sole Owner/Proprietorship</td><td><input type="checkbox"/> State</td></tr><tr><td><input type="checkbox"/> Other:</td><td></td></tr></table>			<input type="checkbox"/> City	<input type="checkbox"/> Hospital District/Authority	<input type="checkbox"/> Corporation	<input type="checkbox"/> Limited Liability Company (LLC)	<input type="checkbox"/> County	<input type="checkbox"/> Limited Liability Partnership (LLP)	<input type="checkbox"/> Hospital	<input type="checkbox"/> Limited Partnership (LP)	<input checked="" type="checkbox"/> Limited (LTD)	<input type="checkbox"/> Partnership	<input type="checkbox"/> Sole Owner/Proprietorship	<input type="checkbox"/> State	<input type="checkbox"/> Other:	
<input type="checkbox"/> City	<input type="checkbox"/> Hospital District/Authority																
<input type="checkbox"/> Corporation	<input type="checkbox"/> Limited Liability Company (LLC)																
<input type="checkbox"/> County	<input type="checkbox"/> Limited Liability Partnership (LLP)																
<input type="checkbox"/> Hospital	<input type="checkbox"/> Limited Partnership (LP)																
<input checked="" type="checkbox"/> Limited (LTD)	<input type="checkbox"/> Partnership																
<input type="checkbox"/> Sole Owner/Proprietorship	<input type="checkbox"/> State																
<input type="checkbox"/> Other:																	
<ul style="list-style-type: none"><li>• Provide a copy of the IRS letter assigning the federal Employer Identification Number (EIN).</li><li>• Provide a copy of the Certificate of Filing from the Office of the Secretary of State.</li><li>• Attach an organizational chart showing the ownership structure. See Example in the instructions.</li></ul>																	

### Section 3 – Physician Ownership

Does this hospital have physician owners? <input checked="" type="radio"/> Yes <input type="radio"/> No
If yes was marked, also complete Section 16, Physician Ownership Addendum.

Name of Multiple Location Hospital:

DHR Health Brownsville

Form 3229

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#### Section 4 – Hospital Services

Check all services offered:

- ☒ Medical (special hospitals only)
- ☒ Surgery (general hospitals only)
- ☐ Obstetrical Care (general hospitals only)
- ☒ Clinical Laboratory Services (required contracted or onsite)
- ☒ Diagnostic X-ray Services (required)
- ☒ Emergency Department
- ☐ Emergency Treatment Room (required if no Emergency Department)
- ☐ Pediatric (if 15 or more beds)
- ☐ Comprehensive Medical Rehabilitation
- ☐ End Stage Renal Disease (ESRD) Acute Services\* (in an identifiable part of the hospital)
- ☐ Mental Health Services (in an identifiable part of the hospital)
- ☐ Inpatient Chemical Dependency (in an identifiable part of the hospital)
- ☐ Outpatient Chemical Dependency (in an identifiable part of the hospital)
- ☐ Other Definitive Medical or Surgical Treatment: \_\_\_\_\_

\*Answer the questions below if ESRD stations are provided for treatment within a designated area of the hospital.

1. What patient populations are being served? ☐ Pediatric ☐ Adult
2. Does the hospital provide peritoneal dialysis? ☐ Yes ☐ No
3. How many stations does the hospital have (not included in bed count)? \_\_\_\_\_

#### Section 5 – All State Waivers

Does this location currently have a state waiver? ☐ Yes ☒ No

Does this location currently have a state waiver for the Emergency Department? ☐ Yes ☒ No

If yes was marked, provide a copy of the waiver.

#### Section 6 – Other Services

Select any of the following, if applicable:

- ☐ Long Term Acute Care Hospital
- ☐ Critical Access Hospital
- ☐ Skilled Nursing Unit
- ☐ Children's Hospital
- ☒ None

Name of Multiple Location Hospital:

DHR Health Brownsville

Form 3229

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## Section 7 – Licensed Beds and Fees

1. How many total licensed beds are at this hospital location (total bed design capacity of this hospital only)? 59

**Note:** A change in the bed design requires prior approval and possible fees.

2. Total fee is \$39 per bed. Amount paid: \$2,301.00

Make checks payable to Texas Health and Human Services Commission.

2. How many emergency treatment room beds and/or emergency department beds are at this hospital location? 2

**Note:** This count is not included in the licensed bed count above and will not affect fees. A minimum of one bed is required.

3. Provide the total number of licensed beds in each unit or area of service at this hospital location: 59

Medical/Surgical (may include pediatric beds if pediatric bed count is less than 15 beds): 56

ICU/CCU: 3

Postpartum:

Intermediate Care:

Adolescent:

Universal Care:

Pediatric (if 15 or more beds):

Neonatal ICU:

Skilled Nursing:

Continuing Care Nursery:

Comprehensive Medical Rehabilitation:

Antepartum:

Mental Health:

Labor/Delivery/Recovery/Postpartum:

Chemical Dependency:

## Section 8 – Hospital Accreditation Only

Check the category that applies and attach a copy of the most recent hospital letter or certificate of accreditation.

☒ Joint Commission (JC) ☐ American Osteopathic Association (AOA)

☐ DNV GL ☐ Center for Improvement in Healthcare Quality (CIHQ)

☐ Not Accredited

## Section 9 – Medicare Certification

Is the hospital certified to participate in the Title XVIII Medicare Program? ☒ Yes ☐ No

If yes, provide the hospital's CMS Certification number (CCN): 450869

## Section 10 – SAFE-ready Facility

Is your facility a SAFE-ready facility? ☐ Yes ☒ No

"SAFE-ready facility" means a health care facility designated as a Sexual Assault Forensic Exam-ready facility under Texas Health and Safety Code (HSC) Section 323.0015. A SAFE-ready facility employs or contracts with a sexual assault forensic examiner or uses a telemedicine system of sexual assault forensic examiners to provide consultation to a licensed nurse or physician when conducting a sexual assault forensic medical examination.

## Section 11 – Fire Safety Survey

Include a copy of a fire safety survey indicating approval by the local fire authority in whose jurisdiction the facility is based that is dated no earlier than one year prior to the application date, as required by HSC §241.023(d)(1) and 25 Texas Administrative Code §133.22(a)(6). Annual fire safety inspections are required for continued licensure status.

Name of Multiple Location Hospital:

DHR Health Brownsville

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## Section 12 – Patient Transfer Policy/Memorandum of Transfer/Patient Transfer Agreement

- ☒ Submit a copy of the hospital's Memorandum of Transfer and the Patient Transfer Policy developed in accordance with the rules governing patient transfer policies and agreements, signed by both the chairman and secretary of the hospital's governing body attesting to the date of adoption of the policy and the policy's effective date.
- ☐ Submit copies of all Patient Transfer Agreements between the hospital and another hospital licensed under HSC Chapter 241, developed in accordance with the rules governing hospital patient transfer policies and agreements (unless you have a written waiver granted by HHSC). If you have a written waiver, attach a list of hospitals that your hospital has agreements with and include the effective dates of the agreements. Only submit agreements between hospitals that are licensed under HSC Chapter 241.
- ☒ Exception to submission of Patient Transfer Agreement – Check this box if you only plan to transfer patients to your parent hospital.

## Section 13 – Signature and Attestation

I attest that the owner meets the requirements of 25 Texas Administrative Code, Chapter 133, Hospital Licensing Rules, and that all information contained in this application is true and correct. I attest that all copies submitted with the application are original copies or copies of the original documents. In compliance with HSC §241.022(c)(1) and the Hospital Licensing Rules, I attest that the physicians on the medical staff of this hospital are currently licensed by the Texas Medical Board and are qualified legally, professionally and ethically for the positions to which they are appointed.

  
Chief Executive Officer (CEO) Signature

10/06/2021  
Date Signed

Manish Singh, MD

Chief Executive Officer

CEO Printed Name

Title

956-362-7151

m.singh@dhr-rgv.com

Area Code and Phone No.

Email Address

## Section 14 – Hospital Administrator (Onsite administrator in charge of day-to-day operations)

Aida Coronado Garcia

Senior Vice President, DHR Health Brownsville

Administrator

Title

956-342-1890

a.coronadogarcia@dhr-rgv.com

Area Code and Phone No.

Email Address

Name of Multiple Location Hospital:  
DHR Health Brownsville

### Section 15 – Ownership Addendum

Complete if partnership or corporation and attach additional pages, if necessary. ☐ N/A

☒ **Owner is Partnership** (List each individual who is a general partner.)

Name: RGV Med, LLC	Social Security No.: NA
Name: _____	Social Security No.: _____
Name: _____	Social Security No.: _____
Name: _____	Social Security No.: _____

☐ **Owner is Corporation** (List each individual who has an ownership interest of 25% or more in the corporation.)

### Section 16 – Physician Ownership Addendum

Complete if hospital has physician owners with each Texas Medical Board license number and attach additional pages, if necessary. ☐ N/A

Name: _____	License No.: _____	Owns _____ %
Social Security No.: _____	Address: _____	
Name: _____	License No.: _____	Owns _____ %
Social Security No.: _____	Address: _____	
Name: _____	License No.: _____	Owns _____ %
Social Security No.: _____	Address: _____	
Name: _____	License No.: _____	Owns _____ %
Social Security No.: _____	Address: _____	
Name: _____	License No.: _____	Owns _____ %
Social Security No.: _____	Address: _____	

## Chapter 241 Hospital Licensing Waiver Request

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Doctors Hospital at Renaissance, Ltd. (DHR Health) (License # 007971) requests waiver of Texas Health and Safety Code, Subchapter B. Licensing of Health Facilities, Chapter 241, Section 241.023(c-1)(2) (Chapter 241 and/or Code) and applicable regulations Chapter 25 Texas Administrative Code (TAC) Section 133.21(c)(4)(A), relating to Section 133.2(47)(B)(ii).

Chapter 241 Section 241.023(c-1) prescribes the conditions under which the Texas Health and Human Services Commission (HHSC) may issue a license for multiple hospitals. DHR Health seeks a waiver of one of these conditions. Specifically, DHR Health seeks a waiver of Code Section 241.023(c-1)(2) which provides that “all buildings in which inpatients receive hospital services are within a 30-mile radius of the main address of the applicant.” DHR Health is in compliance with all other conditions under Chapter 241, including the conditions for a multiple hospital license under Section 241.023(c-1).

In accordance with the waiver request of Chapter 241.023(c-1)(2), DHR Health seeks waiver of the applicable regulations, 25 TAC Section 133.21(c)(4)(A), relating to Section 133.2(47)(B)(ii). Section 133.21(c)(4) “Scope of hospital license”, provides that multiple hospitals may be licensed under one license provided that several conditions are met, including the condition that “(A) [t]he hospitals must comply with the requirements of multiple hospitals under a single license as specified under § 133.2(41) of this title (relating to Definitions).”<sup>1</sup>

As detailed in DHR Health’s Form 3229 Application for a License to Operate a Multiple Location Hospital, DHR Health is adding a new general hospital facility (DHR Health Brownsville) located in Brownsville, TX<sup>2</sup>, which is 47.14 miles (as the crow flies) away from DHR Health’s main address (primary hospital location).<sup>3</sup> See Appendix A. Consequently, as DHR Health Brownsville is located more than 30 miles away from DHR Health’s main address, a waiver is required to operate DHR Health Brownsville under DHR Health’s existing license.

DHR Health aims to include DHR Health Brownsville under its existing license to avoid any potential federal regulatory issues due to DHR Health’s status as a physician-owned hospital. As is provided in more detail below, the granting of the waiver will not adversely affect the health and safety of hospital patients, employees or the general public or the hospital’s participation in the federal Medicare program. Moreover, granting the waiver requested would facilitate the creation and operation of the hospital, and would be appropriate when balanced against the best interests of the individuals to be served by the hospital. On the contrary, not granting the waiver could impose an unreasonable hardship on the hospital in providing adequate care for patients by creating potential federal regulatory issues.

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<sup>1</sup> Although 25 TAC Section 133.21(c)(4)(A) references Section 133.2(41) as the applicable condition for a multiple hospital license, we believe the proper reference should be to 25 TAC Section 133.2(47) definition of “Premises” as subpart (47) aligns with the statutory conditions in Chapter 241, Section 241.023(c-1) whereas subpart (41), definition of “Pediatric and adolescent hospital” does not. Section 133.2(47)(b)(ii) defines “Premises” and tracks Code Section 241.023(c-1)(2), providing that “Premises” includes multiple buildings if, amongst other conditions, “(ii) all buildings in which inpatients receive hospital services are within a 30-mile radius of the primary hospital location;”.

<sup>2</sup> DHR Health Brownsville general hospital facility address: 4705 N. Expressway, Brownsville, TX 78526.

<sup>3</sup> DHR Health main address: 5501 S. McColl Rd., Edinburg, TX 78539.



**Waiver Criteria and Justification****(1) Provide evidence to support why the requested waiver will not adversely affect the health and safety of the hospital patients, employees, or the general public;**

Granting a waiver of the 30 mile condition for multiple hospitals will not adversely affect the health and safety of the hospital's patients, employees, or the general public for several reasons:

**First and foremost**, the DHR Health Brownsville will operate in compliance with all applicable federal, state, and local laws, regulations, and ordinances related to hospital health and safety standards, including but not limited to, the Medicare Conditions of Participation, state and local fire code standards, and Texas hospital licensing rules. No waiver of any rules related to the health and safety of patients, staff, or the general public is being sought.

**Second**, DHR Health operates under the highest quality standards. Our inpatient hospital facilities are accredited by The Joint Commission (TJC), and must meet the most rigorous performance standards. As is discussed below, DHR Health Brownsville will be completely integrated into the DHR Health system, including a requirement for DHR Health Brownsville to receive accreditation by the TJC and being subject to the same quality standards currently governing our inpatient facilities and enforced through our integrated quality assurance team. See Appendix B, TJC Accreditation

**Third**, DHR Health Brownsville will be operated as a general hospital with 39 medical/surgical inpatient beds at single occupancy (59 at double occupancy), and the capabilities and resources to provide necessary care to the general public, including regularly maintaining, at a minimum: clinical laboratory services, diagnostic X-ray services, treatment facilities, including surgery, a 24/7 basic emergency department, intensive care unit with 3 beds, and 7 nursing stations with around-the-clock nursing care.

DHR Health Brownsville will offer the following services:

Medical	Surgical
Family Practice	Urology
Internal Medicine	Gynecological Oncology
Endocrinology	General Surgery
Neurology	Gastroenterology
Radiology	ENT
Pathology	Hand Surgery
Anesthesiology	Bariatric Surgery
Emergency Medicine	Cardiology
	Colorectal Surgery

**Fourth**, the DHR Health Brownsville facility can provide additional capacity during a public health emergency. The facility is ready-made that will be brought online in short notice and in the case of a COVID-19 surge or future infectious disease outbreak / pandemic, can be quickly converted for higher capacity. The facility can be converted overnight into double occupancy and can operate as a freestanding, isolated, and dedicated infectious disease hospital.

**Fifth**, the DHR Health Brownsville facility will comply with all applicable multiple hospital requirements with the exception of being located within 30 miles of the main address. DHR Health Brownsville will be fully integrated into the DHR Health organization and governance structure, unless otherwise required by law or regulation. DHR Health currently operates four inpatient facilities under this model (general acute care hospital, rehabilitation hospital, women's hospital, and behavioral hospital). DHR Health Brownsville will be integrated into the unified DHR Health system and operated in the same manner as all four of our current inpatient facilities.

**Texas Health and Safety Code §241.023(c-1) / 25 TAC § 133.2(47):**

- (1) all buildings in which inpatients receive hospital services and inpatient services of each of the hospitals to be included in the license are subject to the control and direction of the same governing body;**
  - DHR Health Brownsville, including all buildings in which inpatients are to receive hospital services and inpatient services is completely owned and operated by DHR Health and is subject to the control and direction of DHR Health's governing body, the Board of Managers. See Appendix C, Deed of Trust; Appendix D, DHR Health Organizational Chart.
- (2) all buildings in which inpatients receive hospital services are within a 30-mile radius of the main address of the applicant;**
  - *A waiver of this provision is being sought.*
- (3) there is integration of the organized medical staff of each of the hospitals to be included in the license;**
  - There will only be one unified medical staff for DHR Health, which includes DHR Health Brownsville. See Appendix E, DHR Health Medical Staff Bylaws.
- (4) there is a single chief executive officer for all of the hospitals who reports directly to the governing body and through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of the hospital;**
  - There is a single chief executive officer for all of DHR Health. The Senior Vice President for DHR Health Brownsville will serve as the facility's top administrator and will report directly to DHR Health's Chief Executive Officer, who in turn reports directly to DHR Health's governing body - the Board of Managers.
  - All administrative authority flows through DHR Health's Chief Executive Officer who exercises control and surveillance over all administrative activities of the hospital. Support and administrative services such as, but not limited to, legal, accounting, human resources, payroll, revenue cycle, and information technology will be provided by DHR Health's existing centralized infrastructure and departments. See Appendix D, DHR Health Organizational Chart.
- (5) there is a single chief medical officer for all of the hospitals who reports directly to the governing body and who is responsible for all medical staff activities of the hospital;**
  - The DHR Health Brownsville Chief Medical Officer will report directly to the DHR Health (system) Chief Medical Officer who is responsible for all medical staff activities of DHR Health and who reports directly to DHR Health's governing body - the Board of Managers. See Appendix D, DHR Health Organizational Chart.
- (6) each building of a hospital to be included in the license that is geographically separate from other buildings of the same hospital contains at least one nursing unit for inpatients, unless providing only diagnostic or laboratory services, or a combination of diagnostic or laboratory services, in the building for hospital inpatients; and**
  - DHR Health Brownsville will have 7 nursing stations: 4 on the first floor (Emergency Dept. 1; Post-Op 2; and Pre-Op 1); and 1 nursing station on the second floor and 2 on the third floor.

**(7) each hospital that is to be included in the license complies with the emergency services standards:**

**(A) for a general hospital, if the hospital provides surgery or obstetrical care or both; or**

- DHR Health Brownsville is a general hospital that will provide surgery services but not obstetrical services. DHR Health Brownsville complies with all emergency service standards in compliance with 25 TAC § 133.41(e).

**(B) for a special hospital, if the hospital does not provide surgery or obstetrical care.**

- DHR Health Brownsville is a general hospital facility.

DHR Health Brownsville will comply all multiple hospital requirements in 25 TAC § 133.21(c)(4), including providing emergency services in compliance with 25 TAC §133.41(e), and meeting the requirements for new construction in 25 TAC § 133.162, and necessary documentation.

**Finally**, granting the waiver will increase access for Brownsville residents to the most advanced health care services available in the Rio Grande Valley. Patients at the DHR Health Brownsville will be provided with excellent care provided under the highest standards for quality. However, should a patient require a higher level of care than can be provided at DHR Health Brownsville, through patient transfer, the patient will have direct access to DHR Health's vast offerings of advanced services.

With over 70 specialties and sub-specialties and 600+ physicians on our medical staff required to take emergency call, DHR Health has the most extensive around-the-clock on-call coverage of any hospital in the Rio Grande Valley. DHR Health has continually invested in expanding the availability of advanced treatments and technologies. For example, DHR Health provides:

- The region's first and only Level I Comprehensive Trauma facility with the highest level of orthopedic trauma coverage with the Valley's only orthopedic traumatologist;
- the most comprehensive neurology services, including neuro-intervention, 3 full-time neurosurgeons, a dedicated neurological Intensive Care Unit (ICU), and the *first* and *only* Certified Comprehensive Stroke Center by The Joint Commission in the RGV;
- the only kidney transplant program in the Rio Grande Valley;
- the area's only structural heart program; and
- the most extensive coverage of any hospital in the region for Ear, Nose and Throat (ENT), Oral-Maxi facial (OMF), and ophthalmology services, to name a few.

DHR Health's main general acute care hospital is a designated Level I Comprehensive Trauma Facility and our health system serves as the flagship teaching hospital for the University of Texas Rio Grande Valley School of Medicine's with 155 accredited training positions in general surgery, family medicine, internal medicine, obstetrics and gynecology, cardiology, gastroenterology, sports medicine, urology, and hospice and palliative care. These are critical services for a high-level trauma center and teaching hospital and their availability substantially increases the level of life-saving and care for the residents of the Rio Grande Valley. With the opening of the DHR Health Brownsville, the residents of Cameron County will have increased access to the Rio Grande Valley's most advanced health care services.

Consequently, the granting of the waiver to allow the DHR Health Brownsville to operate under DHR Health's existing license would not in any way adversely affect the health and safety of hospital patients, employees, or the general public.

**(2) Indicate how it was determined that granting of the waiver would not adversely impact the hospital's participation in the federal Medicare program or accreditation by a Centers for Medicare and Medicaid Services-approved organization;**

Granting the requested waiver will not adversely impact the hospital's participation in the federal Medicare program or accreditation by The Joint Commission (TJC), the Medicare approved accreditation organization used by DHR Health. Conversely, the granting of the waiver will facilitate the enrollment of the DHR Health Brownsville in Medicare under DHR Health's existing Medicare provider agreement. Operating DHR Health Brownsville under DHR Health's existing license will provide clarity and avoid any potential issues related to the Medicare provider-based regulations and DHR Health's status as a physician-owned hospital.

As a physician-owned hospital, DHR Health is restricted in its ability to expand by the physician self-referral law (Stark).<sup>4</sup> In order to participate in the Medicare program, the Stark law requires physician-owned hospitals to have had a CMS provider agreement as of December 31, 2015 and prohibits existing physician-owned hospitals from acquiring a new provider agreement.<sup>5</sup> Additionally, the Stark law limits the number of operating rooms, procedure rooms, and beds that a physician-owned hospital can operate to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010,<sup>6</sup> with some exceptions.<sup>7</sup> DHR Health was granted an exception to expand in 2015.<sup>8</sup>

To comply with the Medicare provider-based regulations, DHR Health Brownsville will be enrolled in the Medicare program under DHR Health's existing Medicare provider agreement as a "remote location of a hospital".<sup>9</sup> For the purposes of clarity and avoiding any potential issues, DHR seeks to license DHR Health Brownsville under the same license as DHR Health's inpatient facilities in Edinburg, TX.

**(3) Describe how not granting the waiver would impose an unreasonable hardship on the hospital in providing adequate care for patients;**

Not granting the 30-mile waiver would impose an unreasonable hardship on the hospital because granting the waiver would avoid potential federal regulatory issues, and granting the waiver while not impacting or implicating the safety of patients, employees or the public.

**(4) Describe how the waiver would facilitate the creation or operation of the hospital; and**

Granting of the waiver would allow DHR Health to proceed forward with the creation and operation of DHR Health Brownsville by removing regulatory barriers that would not impact the quality of care delivered or the safety of patients, staff, and the general public.

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<sup>4</sup> Section 1877 of the Social Security Act, 42 U.S.C. §1395nn.

<sup>5</sup> 42 U.S.C. §1395nn(i)(1)(A).

<sup>6</sup> 42 U.S.C. §1395nn(i)(1)(B).

<sup>7</sup> 42 U.S.C. §1395nn(i)(3).

<sup>8</sup> See <https://www.federalregister.gov/documents/2015/09/17/2015-23363/medicare-program-approval-of-request-for-an-exception-to-the-prohibition-on-expansion-of-facility>.

<sup>9</sup> 42 C.F.R. §413.65(a): "Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section....".

**(5) Explain how the waiver would be appropriate when balanced against the best interests of the individuals served or to be served by the hospital.**

The granting of the 30-mile waiver would be appropriate because it would be in the best interests of the individuals to be served at DHR Health Brownsville by increasing access to care and advanced health care services in the Brownsville, Cameron County, TX area. Additionally, as is expanded on above, granting the waiver would not adversely affect the health and safety of the hospital's patients, employees, or the general public in any manner.

The City of Brownsville, Cameron County, Texas is situated on the U.S.-Mexico southern border in the Rio Grande Valley of Texas. Cameron County is one of the four southern-most counties in Texas along with Hidalgo, Starr, and Willacy. Cameron County has a population of about 425,000.<sup>10</sup> The City of Brownsville, with 183,000 residents, is the largest city in Cameron County.

**Applying the ‘inpatient acute bed per capita’ ratio, a widely-used metric to measure and compare the adequacy of inpatient hospital capacity across regions demonstrates that the Rio Grande Valley, including the City of Brownsville is under-bedded.** The average number of inpatient acute beds for the West South Central Region of the country, which includes Texas, Louisiana, Oklahoma, and Arkansas, is 3.48<sup>11</sup>. The Rio Grande Valley, however, falls below the regional ratio.

<b>Rio Grande Valley</b>	<b>Inpatient Acute Care Bed Per Capita</b>	<b>% Below West South Region<sup>12</sup></b>
City of Brownsville <sup>13</sup>	2.5	-29%
Cameron County <sup>14</sup>	2.6	-26%
Hidalgo County <sup>15</sup>	2.1	-38%

The national average number of acute beds per 1,000 people is 2.4.<sup>16</sup> However, because of disparities in socio-economic and health factors, a more accurate assessment requires a comparison between similarly situated regions. The South West Central Region is comparable to the Rio Grande Valley in important

<sup>10</sup> U.S. Census Cameron County, Texas Quick Facts: <https://www.census.gov/quickfacts/cameroncountytexas>

<sup>11</sup> Beckers Hospital Review 308 Stats on Acute Care Beds Hospital Referral Centers.  
<https://www.beckershospitalreview.com/patient-flow/308-stats-on-acute-care-beds-by-hospital-referral-region.html>

<sup>12</sup> *Id.*

<sup>13</sup> Brownsville has two general acute hospitals, Valley Baptist Medical Center – Brownsville (240 acute licensed beds), and Valley Regional Medical Center (214 acute licensed beds) [DSHS Hospital Directory 03/31.2021] for a population of 183,000 in the City of Brownsville and the many surrounding communities including San Benito, South Padre Island, Los Fresnos, Port Isabel and many others.

<sup>14</sup> Cameron County has four general acute hospitals, Valley Baptist Medical Center – Harlingen (534 acute licensed beds), Harlingen Medical Center (112 acute licensed beds), Valley Baptist Medical Center – Brownsville (240 acute licensed beds), and Valley Regional Medical Center (214 acute licensed beds) [DSHS Hospital Directory 03/31.2021] for a population of 425,000 based on latest US Census estimates.

<sup>15</sup> Hidalgo County has seven inpatient general acute hospitals – DHR Health (363 acute licensed beds), South Texas Health System's hospitals: Edinburg Regional/McAllen Medical/McAllen Heart Hospital/Cornerstone (687 acute licensed beds), Rio Grande Regional (320 acute licensed beds), Knapp Medical Center (220 acute licensed beds), and Mission Regional (254 acute licensed beds) [DSHS Hospital Directory 03/31.2021] for a population of 869,000 based on latest US Census estimates.

<sup>16</sup> *Supra* n. 11.

ways. Texas, Louisiana, Oklahoma, and Arkansas all rank within the top ten states with high rates of diabetes and obesity.<sup>17</sup> Additionally, the other states rank in the top ten states in terms of poverty levels, however, no state-wide poverty level reaches the heights experienced in the Rio Grande Valley.<sup>18</sup> Consequently, given the high rates of chronic disease and poverty levels, it is not surprising that the South Central Region would have a higher need for inpatient acute beds per capita (i.e. the higher rates of poverty and disease, the more need for hospital beds).

The two remaining counties in the Rio Grande Valley are rural, lack access to care, and are low in population. Starr County has approximately 65,000 persons and a small, basic general acute public hospital – Starr County Memorial Hospital (SCMH). DHR Health is affiliated with SCMH and provides emergency department, hospitalist, and general surgery coverage at the hospital to ensure it is able to maintain a higher level of care. Higher acuity patients in Starr County are generally seen in Hidalgo County area hospitals, including DHR Health. However, DHR Health is working with SCMH to increase specialized care in Starr County to reduce the need for residents to travel to Hidalgo County for care. Starr County residents now have access to specialties such as endocrinology, urology, cardiology and outpatient general surgery and orthopedics as a result of the affiliation with DHR Health. Willacy County, in the Northeastern part of the Rio Grande Valley is home to approximately 23,000 persons and has no hospitals. Generally, Willacy County patients are seen in Cameron County hospitals.

The Rio Grande Valley, and Brownsville in particular, has a shortage of inpatient acute beds due to a variety of factors, including, but not limited to:

1. Health Factors
  - a. Epidemic of diabetes (30%, with another 32% pre-diabetic), combined with high rates of obesity (51%) and related health issues, including cardiovascular, liver, peripheral artery and chronic renal disease, and retinopathy, and behavioral issues.
2. Access to Health Care Factors
  - a. High Poverty Rate (40%)
  - b. Highest Uninsured Rate in the Country (29% - 33%)
  - c. Health Professional Shortages (1,700+ physician shortage, and nurse shortages)
3. Growing Population and Needs

**The population of Brownsville, and the Rio Grande Valley in general, is sicker, more impoverished, and faces significant obstacles to access care.** The high rates of poverty and chronic diseases translate into a situation where a large proportion of the population needs access to preventative medical care and disease management yet cannot afford health insurance or out-of-pocket costs.

Additionally, many residents of Cameron County lack accessible transportation options. The area also faces health professional shortages, further limiting access. DHR Health is the primary teaching site for the University of Texas Rio Grande Valley School Of Medicine, and as their natural partner, we want to continue to increase access to health care by expanding residency programs to the Brownsville area. These factors result in many patients foregoing preventative care or disease management and seeking care while in crisis via hospital emergency rooms, which increases the overall cost of treatment as well as the demand and need for inpatient acute beds

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<sup>17</sup> <https://www.stateofobesity.org/diabetes/>

<sup>18</sup> <https://www.usnews.com/news/best-states/slideshows/states-with-the-highest-poverty-rates-in-the-us?onepage>

Cameron County is growing and is **expected to add an additional 40,000 residents** within the next five years, the majority of which will be in Brownsville. Additionally, two new major projects currently in development for Brownsville will generate thousands of new jobs, billions of dollars in economic impact and substantially increase the Brownsville area's population.

Consequently, the City of Brownsville is in need of additional inpatient acute care beds due to an epidemic of chronic disease, and a growing and impoverished population that lacks sufficient access to preventative medical care to manage their disease. Data indicates that both the city and region are falling behind similarly situated regions in terms of acute inpatient beds per capita. Granting the waiver will allow DHR Health to proceed forward and add additional bed capacity in Brownsville and increase access to care in a much underserved area.